STAT PROFILE®
pHOx®

Stat Profile® pHOx® Series Analyzers

Advanced User Applications Manual

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nova biomedical

pHOx Series Advanced User Applications Manual

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Revision History

Stat Profile® pHOx® Series Advanced User Applications Manual

Part Number and Ordering Information

The *Stat Profile® pHOx® Series Advanced User Applications Manual* can be ordered from Nova Biomedical Order Services. Write or call:

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Note: Important Information — Nova Analyzers

The following is important information regarding the proper operation and control of Nova analyzers. With the advent of the requirements that the end user specifically follows **all** directions for use from the manufacturer, Nova becomes a partner with the user and becomes responsible for providing instructions that will virtually guarantee that the analyzer is in control. This requires Nova to provide instructions on maintenance and control which are virtually foolproof in regards to assuring that an analyzer is in control.

In addition to asking that all operators perform the maintenance and calibration procedures described in this manual, we also recommend that **only** Nova reagents, calibrators, cleaning agents, and controls be run through the analyzers. These are the **only** materials that we have fully characterized and tested. We have neither tested the performance nor determined the long term effects of products provided by others for use on our instruments. Confirming that an analyzer is in control by using reagents and controls not certified by Nova Biomedical cannot be guaranteed by Nova, and Nova will not be responsible for the consequences. Users who elect to use reagents, standards and/or controls from other producers should confirm by the appropriate testing protocols from those other manufacturers that Nova's instrumentation is in control. This testing verification should also include a means of troubleshooting when the instrument is not in control, since Nova Biomedical cannot, in the present environment, provide that service. Since Nova Biomedical does not know the formulations of the reagents and controls used by other manufacturers, including the levels of surfactants, preservatives, viscosity adjusters, and other additives that may be used Nova cannot guarantee that the results obtained on controls or patient samples will be correct when these products are used. There is also no way to determine whether there will be long term or short term adverse effects on sensor performance, sensor life, tubing or flow cell degradation, or on data quality/accuracy or reliability.

Nova Biomedical manufactures totally integrated systems to assure proper analyzer performance. We cannot characterize all products that might be used on Nova analyzers, nor can we control changes that other manufacturers might choose to make to their products. Therefore, use of these products with a Nova analyzer must be the responsibility of the individual end user and of that manufacturer rather than Nova.

User modification of an *in vitro* diagnostic device is also regulated. Modification of the product includes use of untested products or products which have not been tested to determine substantial equivalency and safety and effectiveness in use with Nova analyzers.

Nova Biomedical's manuals include the specific information needed for the proper maintenance, qualification, and operation of Nova Biomedical Analyzers. If the user follows the directions in these manuals, they should have very few problems. In the case where they need assistance from Nova Biomedical in troubleshooting their systems, we will stand ready to assist them in any and all ways necessary.

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1 Introduction

This section describes the major components of the Stat Profile pHOx Series Analyzers. The analyzer is initially installed by a factory authorized representative.

> ***CAUTION:*** *The pHOx Series Analyzers are designed to be left on with adequate fluids at all times. This is necessary to prevent crystallization of salts in the fluid lines and cuvette. If it is to be shut down indefinitely, purge all fluid lines with distilled water and then with air. The purge sequence is selected from the Operational Menu.*

1.1 Display and Door

The display is a liquid crystal display (LCD). To adjust the display intensity, use the right (darker) or left (lighter) arrow key while displaying the Ready or Not Ready screen. Prompts, menus, status information, error messages, patient results, etc. are displayed on the screen. The default language is English. (Other languages can be selected through the setup menu.)
The door may be opened to access the analytical compartment of the system. There is an inside latch that is easily released when you pull at the bottom right side of the door.

1.2 Keypad

The primary input device is the keypad. It has the digits (0 thru 9), a decimal point, a dash, an ENTER key, arrow keys (up, down, left, and right), and analyze keys (syringe and capillary icons). There are also 4 Soft Keys whose function is determined by the legend displayed just above it on the LCD display: Print, Exit, Cancel, Menu, etc.

1.3 Printer

The internal printer will be able to print patient results, list the analyzer's setup information, error log, etc.

1.4 Sampler

The sampler allows for the aspiration of the sample. The sampler has 2 sampling positions: horizontal for the aspiration of a sample from a capillary tube and inclined for the aspiration of the sample from a syringe. No special adapters are required to aspirate a sample from a capillary tube. The capillary or syringe positions are selected by pressing the Black Capillary key or the White Syringe key.

1.5 Sensor Module

STP pHOx Basic
The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains 2 air detectors.
The sensor module geometry is an interlaced configuration with the reference sensor at the top of the sensor module, PCO_2 sensor on the left side and the pH and PO_2 sensors on the right side. A window in the door allows flow path visibility and is augmented by a backlight.

STP pHOx
The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains the hematocrit impedance sensor and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference sensor at the top of the sensor module, 3 sensors on the left side, 2 sensors on the right side. In addition to the Hct sensor located in the preheater, there are 6 sensors: Reference sensor, Na^+, PCO_2, SO_2 (optic), pH, and PO_2. A window in the door allows flow path visibility and is augmented by a backlight.

STP pHOx Plus
The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains the hematocrit impedance sensor and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference sensor at the top of the sensor module, 4 sensors on the left side, 4 sensors on the right side. In addition to the Hct sensor located in the preheater, there are 9 sensors: Reference sensor, pH, Na^+, PCO_2, SO_2 (optic), and PO_2, glucose, K^+, and Cl^- (or Ca^{++}). A window in the door allows flow path visibility and is augmented by a backlight.

STP pHOx Plus C
The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains the hematocrit impedance sensor and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference sensor at the top of the sensor module, 4 sensors on the left side and 5 sensors on the right side. In addition to

the Hct sensor located in the preheater, there are 10 sensors: Reference sensor, pH, Na^+, PCO_2, SO_2 (optic), and PO_2, glucose, K^+, Cl^-, and Ca^{++}. A window in the door allows flow path visibility and is augmented by a backlight.

STP pHOx Plus L

The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains the hematocrit impedance sensor and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference sensor at the top of the sensor module, 4 sensors on the left side, 5 sensors on the right side. In addition to the Hct sensor located in the preheater, there are 10 sensors: Reference sensor, pH, Na^+, PCO_2, SO_2 (optic), and PO_2, glucose, lactate, K^+, and Cl^- (or Ca^{++}). A window in the door allows flow path visibility and is augmented by a backlight.

1.6 Sensors

The Sensors housed in the sensor module are the core of the Stat Profile pHOx Series Analyzers. The methodology used by each sensor are

Sensor	Methodology of Sensor	Basic pHOx	pHOx	pHOx Plus	pHOx Plus/C	pHOx Plus L
pH	Hydrogen ion-selective glass	+	+	+	+	+
PO_2	Polarographic Clark-type	+	+	+	+	+
PCO_2	Severinghaus-type	+	+	+	+	+
SO_2	Reflectance photometry (fiber optics)		+	+	+	+
Hct	Impedance		+	+	+	+
Hb	Impedance/photometry		+	+	+	+
Na^+	Sodium ion-selective		+			
Na^+	Sodium ion-selective glass			+	+	+
K^+	Potassium ion-selective			+	+	+
Cl^-	Chloride ion-selective			+	+	+
Ca^{++}	Calcium ion-selective			+	+	+
Glu	Enzymatic			+	+	+
Lac	Enzymatic					+

The sensors clip into the sensor module, and electrical contact is automatically made.

1.7 Reference Sensor

The Reference Sensor is mounted above the sensor module. It is a solid-state Ag/AgCl sensor and provides the reference voltage for comparison to sample voltages. The exit port of the flow path is located on this sensor.

1.8 Barometric Pressure Module

The Barometric Pressure Module, located on a printed circuit board, continuously monitors the barometric pressure. This barometer can be calibrated against an external barometer, if desired, through the software.

1.9 Pinch Valves

There are 2 pinch valves: one is used to control the flow of the reference fluid and the other one is used to control the flow of fluids exiting the sensor module.

1.10 Peristaltic Pump

The pump is a 6-roller peristaltic pump driven by a stepper motor.

1.11 Calibrator Cartridges, Auto-Cartridge QC, Calibrators, and Solutions

This section covers the calibrator cartridges, auto-cartridge QC, calibrators, and solutions required for proper operation and maintenance of the Stat Profile pHOx Series Analyzers.

1.11.1 Calibrator Cartridge

The calibrator cartridge contains 6 flexible bags in a cardboard carton. One of these is a waste bag to collect the used solutions, controls, and samples. The other 5 bags contain Calibrators: A, B, C, D, and R. Each bag includes a fitment with a septa.
The exposed bag fitments are arranged in a line along the rear of the pack. The septa are pierced during insertion of the pack. The lot number and expiration date are printed on the top front of the pack.

The Reagent Management System (RMS) of the calibrator cartridge automatically enters the calibration values, the lot number, the fluid volumes, and the expiration date to the analyzer's computer after insertion of the calibrator cartridge.

1.11.2 Auto-Cartridge QC

Nova Biomedical's Auto-Cartridge QC is a total automated control system contained within a single on-board QC cartridge. This system allows any level of quality control to be run at any time: either on a programmed schedule or on demand. The Auto-Cartridge QC system reduces costs by eliminating the time and labor required to manually perform quality control.

Stat Profile pHOx Plus/Plus C/Plus L Analyzers

Nova Auto-Cartridges for these analyzers contain 3 levels of blood gas/electrolyte/glucose controls, 2 levels of hematocrit, SO_2%, and hemoglobin controls, plus software that automates running controls and storing quality control data. When the cartridge is installed, all quality control target ranges, lot code, and expiration date information are automatically downloaded to the analyzer. The user then programs the analyzer to automatically analyze up to 3 quality control levels, 3 times per day (a total of 9 analyses per day). If any analyte is outside the target range, it is automatically reanalyzed. If a control value remains out of range, the user is notified.

Stat Profile pHOx Basic Analyzer

Nova Auto-Cartridges for the pHOx Basic Analyzer contain 3 levels of blood gas controls plus software that automates running controls and storing quality control data. When the cartridge is installed, all quality control target ranges, lot code, and expiration date information is automatically downloaded to the analyzer. The user then programs the pHOx Basic Analyzer to automatically analyze up to 3 quality control levels, 3 times per day (a total of 9 analyses per day). If any analyte is outside the target range, it is automatically reanalyzed. If a control value remains out of range, the user is notified.

Stat Profile pHOx Analyzer

Nova Auto-Cartridges for the pHOx Analyzer contain 3 levels of blood gas controls, 2 levels of hematocrit, SO_2%, and hemoglobin controls, plus software that automates running controls and storing quality control data. When the cartridge is installed, all quality control target ranges, lot code, and expiration date information is automatically downloaded to the analyzer. The user then programs the pHOx Analyzer to automatically analyze up to 3 quality control levels, 3 times per day (a total of 9 analyses per day). If any analyte is outside the target range, it is automatically reanalyzed. If a control value remains out of range, the user is notified.

For the pHOx Series Analyzers, all quality control data is automatically stored. Daily and cumulative statistical reports and Levey-Jennings graphs can be printed at any time. This automation assures that quality control is always performed accurately and on schedule, thereby guaranteeing regulatory compliance.

1.11.3 Calibrators and Solutions

Calibrators and solutions are as follows:

1. Basic Calibrator Cartridges: PN 35268, PN 35269, PN 35270, PN 35271
   pHOx Calibrator Cartridge: PN 20807
   Plus Calibrator Cartridges: PN 27610(A), PN 27611(B), PN 27612(C), PN 27613(D)
   Plus L Calibrator Cartridges: PN 34085(A), PN 34086(B), PN 34087(C), PN 34088(D)
2. pH Electrode Conditioning Solution: PN 23397 (pHOx Basic/pHOx)
   Na/pH Conditioning Solution: PN 06858 (pHOx Plus/PlusC/Plus L)
3. Preheater Cleaning Agent: PN 11802 (pHOx Series)
4. PCO_2/TCO_2 Conditioning Solution: PN 06857 (pHOx Plus/PlusC/Plus L)
5. Preheater Deproteinizing Solution: PN 12074 (pHOx Plus/PlusC/Plus L)
6. Electrode Soaking Solution: PN 13409 (pHOx Plus/PlusC/Plus L)
7. Nova Stat Profile pHOx/Plus/Plus C/Plus L SO_2 Calibrators PN 22771 (ampules):
   - External Calibrator Level 1 - SO_2
   - External Calibrator Level 2 - SO_2
8. Nova Stat Profile pHOx Basic Controls:
   - Level 1 - Acidosis, with low pH, high PCO_2, and low PO_2: PN 21652
   - Level 2 - Normal, with normal pH, PCO_2, and PO_2: PN 20676
   - Level 3 - Alkalosis, with high pH, low PCO_2, and high PO_2: PN 20675
   - Multi Pack: PN 25262

   Nova Stat Profile pHOx Controls:

   - Level 1 - Acidosis, with low pH, high PCO_2, low PO_2, low SO_2, & low normal Hct & Hb: PN 22760
   - Level 2 - Normal, with normal pH, PCO_2, and PO_2: PN 22761
   - Level 3 - Alkalosis, with high pH, low PCO_2, high PO_2, SO_2, and normal high Hct & Hb: PN 22762
   - Multi Pack: PN 22763

   Nova Stat Profile pHOx Plus/Plus C Controls (External - ampules):

   - Level 1 - Acidosis: Low pH, high PCO_2, low PO_2, High Na^+, K^+, Cl-, Ca^{++}, and Low normal Glu

- Level 2 - Normal: Normal pH, PCO_2, and PO_2, low SO_2, Low normal Hct and Hb, Normal Na^+, K^+, Cl-, Ca^{++}, and High Glu
- Level 3 - Alkalosis: High pH, low PCO_2, high PO_2, SO_2, Normal high Hct and Hb, Low Na^+, K^+, Cl-, Ca^{++}, and High abnormal Glu

Nova Stat Profile pHOx Plus L Controls (External - ampules):

- Level 1 - Acidosis: Low pH, high PCO_2, low PO_2, High Na^+, K^+, Cl-, Ca^{++}, Glu, and Lac
- Level 2 - Normal: Normal pH, PCO_2, and PO_2, low SO_2, Low normal Hct and Hb, Normal Na^+, K^+, Cl-, Ca^{++}, Glu, and Lac
- Level 3 - Alkalosis: High pH, low PCO_2, high PO_2, SO_2, Normal high Hct and Hb, Low Na^+, K^+, Cl-, Ca^{++}, Glu, and Lac
- Plus Multi Pack: PN 27896
- Plus L Multi Pack: PN 34117

9. Basic Auto-cartridge QC (Internal): PN 35264, PN 35265, PN 35266, PN 35267
   pHOx Auto-cartridge QC (Internal): PN 23930, PN 23931, PN 23932, PN 23933
   Plus/C Auto-cartridge QC (Internal): PN 30643, PN 30644, PN 30645, PN 30646
   Plus L Auto-cartridge QC (Internal): PN 34090, PN 34091, PN 34092, PN 34093

Nova will not be responsible for any of its warranties on sensors, electrodes, tubing, probes, or other parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Some reagent formulations not manufactured by Nova contain acids, concentrated salt solutions, and artificial preservatives which have been shown to cause problems such as shortened sensor/electrode life, sensor/electrode membrane damage, sensor/electrode drift, erratic analytical results, and unacceptable instrument performance.

> **NOTE:** *Refer to the Nova Stat Profile Control insert for storage requirements for these controls. Store all other Nova Stat Profile reagents, standards, and solutions at 15 to 30°C.*

1.12 Movement Of Fluids

To begin an analysis, press the Capillary or Syringe key to move the sampler to either the capillary or syringe position. Present the sample to the probe and press either Aspirate Normal or Aspirate Micro (soft keys). The Aspirate Normal soft key allows for the aspiration of the Full Panel sample, and the Aspirate Micro soft key allows for the aspiration of the Micro Mode sample. The sample is aspirated by the peristaltic pump until the leading edge is detected by either the Full Panel or the Micro Mode air detector. After the aspiration is completed, there is an audible beep and a pop-up display that prompts you to press Analyze after removing the syringe or capillary. The sample is advanced until the leading edge is properly located in front of the sensors. Once all measurements have been completed, the sample is pumped to the waste and the flow path is washed.

Analyzer	Micro Mode Microliters (µL)	Full Panel Microliters (µL)
pHOx Basic	45	70
pHOx	45	70
pHOx Plus	55	115
pHOx Plus C	60	125
pHOx Plus L	60	125

1.13 Operational Overview

The Stat Profile pHOx Series Analyzers are a stand-alone, microprocessor-based instruments for analyzing blood samples. The pHOx Series Analyzers measure pH, PCO_2, PO_2, $SO_2\%$, Hct, Hb, Na^+, K^+, Cl^-, Ca^{++}, Glu, and Lac in heparinized blood. See Section 1.6 to verify which test your pHOx Series Analyzer actually measures.
The analyzer additionally calculates the parameters listed in Section 1.6.
The software allows the control of the following functions:

- Calibration
- Sample analysis
- Quality Control
- Diagnostic and maintenance functions
- System configurations
- Communication interface with external devices
- Storage and retrieval of patient records

After the analyzer is set up and calibrated, it is ready to begin analyzing samples. Samples can be aspirated from syringes, capillaries, open tubes, small sample cups, or ampules. After sample acceptance, patient data can be entered. A limited number of patient records (24) is stored in a "circular" buffer. Once the buffer is full, each new saved record overwrites the oldest record.

1.14 Stat Profile pHOx Series 2-Point Calibration Sequence

The calibration sequence is outlined in Table 1.1 (A, B, or C) according to the order in which the various calibrators are brought into the system for slope determinations, etc.

Table 1.1A Stat Profile pHOx 2-Point Calibration Sequence

Fluid	Function
	Sequence Start
CAL A	CAL A readings for AD1, AD2, AD3, AD4, Hct, pH, PCO_2, PO_2, Na^+
CAL B	CAL B readings for pH and PCO_2
Air	Air reading for PO_2
CAL D	CAL D reading for AD1, AD2, AD3, AD4, Hct, pH, Na^+
CAL C	CAL C reading for pH
	Sensor Slopes are calculated
	ADT thresholds are calculated
	Initialization
	End Calibration

Table 1.1B Stat Profile pHOx Basic 2-Point Calibration Sequence

Fluid	Function
	Sequence Start
CAL A	CAL A readings for AD1, AD2, AD3, AD4, pH, PCO_2, PO_2
CAL B	CAL B readings for pH and PCO_2
Air	Air reading for PO_2
CAL D	CAL D reading for AD1, AD2, AD3, AD4, pH
CAL C	CAL C reading for pH
	Sensor Slopes are calculated
	ADT thresholds are calculated
	Initialization
	End Calibration

Table 1.1C Stat Profile pHOx Plus/Plus C/Plus L 2-Point Calibration Sequence

Fluid	Function
	Sequence Start
CAL A	CAL A readings for AD1, AD2, AD3, AD4, Hct, pH, PCO_2, PO_2, Na^+, K^+, Cl^- (or Ca^{++}), Glucose, Lactate (Plus L)
CAL B	CAL B readings for pH and PCO_2
CAL C	CAL C reading for pH, Na^+, K^+, Cl^-, Glucose, Lactate (Plus L)
CAL D	CAL D reading for AD1, AD2, AD3, AD4, Hct, pH, and Ca^{++}
Air	Air reading for PO_2
	Sensor Slopes are calculated
	ADT thresholds are calculated
	Initialization
	End Calibration

When you troubleshoot flow problems, it is important to view the system as a whole. This means that you must consider all of the various components that interact in order to transport fluids throughout the system. These components include the pump, sampler probe, fluid fountain, rotary valve, pinch valves, and tubing.

The information in this section, along with an understanding of the flow path components and their functions, will give you the knowledge and tools you will need to resolve most of the problems you will encounter.

1.15 Dependencies

NOTE: *Calculated Parameters and Dependencies only apply to an analyzer that calculates and measures them.*

Measured Parameter	Dependencies
Hct	Na^+
Cl^-	Selected for results
Ca^{++}	Selected for results
$SO_2\%$	Hct
Hb	Hct and $SO_2\%$ Priority: 1. If linked with the CO-Ox, then CO-Ox Hb is reported. 2. If no CO-Ox result, calculated result from Hct reading (Hct/3) is reported. 3. If no CO-Ox or measured result, calculated result from Hct reading (Hct/3) is reported. 4. If no CO-Ox, no measured, and no Hct, analyzer reports Default Value (Hb).

Calculated Parameter	Dependencies
BE-b	pH and HCO_3^-
BE-ecf	pH and HCO_3^-
SBC	$SO_2\%$ (or $SO_2\%$ calculated) and BE-b
HCO_3^-	pH and PCO_2
TCO_2	pH and HCO_3^-
$SO_2\%$	$SO_2\%$ (not measured), pH, PCO_2, and PO_2
A	PCO_2
$AaDO_2$	Arterial, PO_2, and A
a/A	Arterial, PO_2, and A
PO_2/FIO_2	Arterial, PO_2, and FIO_2 (entered)
Hb	Hb (not measured) and Hct
nCa^{++}	Ca^{++} and pH
Anion Gap	Cl^-, Na^+, K^+, HCO_3^-
RI	Arterial, PO_2, and $AaDO_2$
$P50$	pH, PCO_2, PO_2,and $SO_2\%$ between 40 and 80 mmHg P50c is reported when PO_2 is outside above limits.
O_2Ct	Hb (measured), $SO_2\%$ (measured or calculated), and PO_2
O_2Cap	Hb (measured), $SO_2\%$ (calculated)
$\dot{Q}sp/\dot{Q}t$	Requires 2 separate blood samples for determination: mixed venous and arterial.

2 Setup

This section describes how to setup the Stat Profile pHOx Series Analyzers. The analyzer is initially installed by a factory authorized representative.

CAUTION: *The pHOx Series Analyzers are designed to be left on with adequate fluids at all times. This is necessary to prevent crystallization of salts in the fluid lines and cuvette. If it is to be shut down indefinitely, purge all fluid lines with distilled water and then with air. The purge sequence is selected from the Operational Menu.*

2.1 Adapting the Program to Your Clinical Requirements with the Setup Menu

Use the Setup Menu to adapt the analyzer to your requirements.

2.1.1 Setup Options

The Setup Menu has the following setup options. The options for each menu are for all tests that the pHOx Series Analyzers can perform. If your analyzer cannot perform all these test, the test that cannot be performed will not be displayed on the menu screens.

- **Results Configuration Menu**
  - Reference and Alert Limits Setup
    pH, PCO_2, PO_2, SO_2%, Hct, Hb, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac
  - Electrode Offsets Setup (See Table 2-1)
    pH, PCO_2, PO_2, SO_2%, Hct, Hb, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac
  - Results Units Setup
    Temperature: °C or °F
    Blood Gas: mmHg or kPa
    pH/H^+: pH or H^+
    Hb: g/dL or mmol/L or g/L
    Glu: mg/dL or mmol/L
    Lac: mmol/L or mg/dL
    Ca^{++}: mmol/L or mg/dL
  - Electrolyte Resolution
    Na^+ Result: xxx.x or xxx. (1 or 0 places after decimal point)
    K^+ Result: xx.x or xx.xx (1 or 2 places after decimal point)
    Cl^- Result: xxx.x or xxx (1 or 0 places after decimal point)
  - Results Suppression: Suppress or not suppress
  - Remote Review: ON or OFF
  - Patient Name: ON or OFF

- Display Temp. Corrected: ON or OFF
- Mandatory Patient ID: ON or OFF

- **Operation Configuration Menu**
  - Analysis Configuration
    Analysis Transmit Mode Manual/Auto
    Transmit Diagnostic Data OFF/ON
    Analysis Print Mode Manual/Auto
    Print Diagnostic Data OFF/ON
    CO-Ox Data Merge Accession nbr/Patient ID
    Set Analyzer ID Number:
    Print Ref. & Alert Limits OFF/ON
  - Calibration Configuration
    Set 2 Point Calibration Frequency 2, 4, 6 hr.
    Transmit Diagnostic Data OFF/ON
    Print Diagnostic Data OFF/ON
    Transmit Drift Data OFF/ON
    Print Drift Data OFF/ON
  - System Configuration
    Set Date Format DD/MM/YY, MM/DD/YY, YY/MM/DD
    Set Time Mode 24/12 hr. Mode
    Date and Time Set
    Measured Barometric Pressure 760 mmHg
    Corrected Barometric Pressure 0.0 mmHg
    Set Default Hb Used in Calculations: 14.3 g/dL
    Set Tone Frequency (100-500Hz): 3500 Hz
  - Analysis Mode: A or B
  - Hb Type: Measured or Calculated
  - Ca^{++}/Cl^{-}: Ca^{++} or Cl^{-} (Select the sensor that is being used for pHOx Plus/Plus L.)
  - STAT Mode: ON or OFF
  - Glu Membrane Test Time: Set the Time
  - Default Panel Set Default Panel Screen: Select a Panel; exit.
- **Communications Menu**
  - Baud (4800, 9600, 19200)
  - Data Bits (7, 8)
  - Stop (1,2)
  - Parity (None, Even, Odd)
  - External Keyboard: Yes or No
  - Co-oximeter attached: Yes or No
  - Bar Code Setup Select the characters for Default, Patient ID, Operator ID, and Accession #
- **Printer** Installed or Not Installed
- **Passwords:** System or Operator
- **Operator Passwords:** ON or OFF
- **Language:** Chinese, English, French, German, Greek, Hungarian, Italian, Japanese, Spanish, and Turkish

Table 2.1 Stat Profile pHOx Series Slope and Offset Limits

Slope and Offset Limits:		Slope	Offset
	pH	lower 0.7000 upper 1.3000	lower -2.000 upper 2.000
	H^+	Lower 0.70 Upper 1.30	lower -15.0 nmol/L upper 15.0
	PCO_2	lower 0.70 upper 1.30	lower -20.0 mmHg upper 20.0
	PO_2	lower 0.70 upper 1.30	lower -30.0 mmHg upper 30.0
	SO_2%	lower 0.70 upper 1.30	lower -20.0 % upper 20.0
	Hct	lower 0.80 upper 1.20	lower -10.0 % upper 10.0
	Hb	lower 0.70 upper 1.30	lower -4.0 g/dL upper 4.0
	Na^+	Lower 0.60 Upper 1.40	lower -20.0 mmol/L upper 20.0
	K^+	lower 0.75 upper 1.25	lower -1.00 mmol/L upper 1.00
	Cl^-	lower 0.70 upper 1.30	lower -20.0 mmol/L upper 20.0
	Ca^{++}	lower 0.70 upper 1.30	lower -0.50 mmol/L upper 0.50
	Glu	lower 0.70 upper 1.30	lower -25 mg/dL upper 25
	Lac	lower 0.70 upper 1.30	lower -1.0 mmol/L upper 1.0

2.2 Password

The first option you should call up is Set Password: either System or Operator.
The System Password, which safeguards the setup parameters, is required to enter the Setup Menu. Set up System Passwords as follows:

1. Press Menu on the Ready screen to display the Operational Menu screen.
2. Press Setup to display the Setup Menu screen.
3. A pop-up Password screen appears. Enter the default password, 0. This is the password until one is officially entered.
4. Scroll down with the arrow keys to the Password option and press Enter. A pop-up screen appears: select System Password.
5. Key in a password number between 1 and 9999 (up to 4 numeric characters) then press ENTER.
6. Proceed to the next setup option or return to the Operational Menu.

The Operator Passwords allows you the ability to enable and to enter 200 unique passwords with privilege levels. When enabled, password entry will be required whenever any of the home screen soft keys, syringe key, or capillary key are pressed. Entry into any one of the protected areas depends on the privilege level assigned to the operator of the analyzer.
There are 3 privilege levels: Privilege Level 1 is the most privileged operator and Privilege Level 3 is the default level.

- Privilege Level 1 operators have access to all areas of the analyzer except those protected by the existing System Password. Level 1 operators do not require PDM review and may override this feature. Level 1 operators can override QC lockout.
- Privilege Level 2 operators have access to all areas of the analyzer except those protected by the existing System Password. Level 2 operators will require PDM review, but may override this feature. Level 2 operators cannot override QC lockout.
- Privilege Level 3 operators have access to analysis only. Level 3 operators will require PDM review before the results are released. Level 3 operators cannot override QC lockout.

Set up Operator Passwords as follows:

1. Press Menu on the Ready screen to display the Operational Menu screen.
2. Press Setup to display the Setup Menu screen.
3. A pop-up Password screen appears. Enter the default password, 0. This is the password until one is officially entered.
4. Scroll down with the arrow keys to the Password option and press Enter. A pop-up screen appears: select Operator Password.
5. Key in a password number, up to 4 numeric characters, into the 3 levels and press ENTER.
6. To enable Operator Passwords, scroll down to Operator Passwords then press the Enter key: Off will turn to On.
7. Proceed to the next setup option or return to the Operational Menu.

2.3 Results Configuration Menu

The Results Configuration Menu screen allows you to set reference and alert limits (Low and High) for all analytes; to adjust electrode offsets for slope and intercept for all analytes; to select units for temperature, pH, blood gas, hemoglobin, glucose, and calcium; and to select electrolyte resolution for sodium, potassium, and chloride (if selected); to turn Remote Review On or Off (operator Password is enabled when On); Global Suppression (Test Results); Patient Name (On or Off); Display Temp. Corrected (On or Off); Mandatory Patient ID (On or Off).

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2.4 Remote Review

The operator passwords are enabled whenever Remote Review is enabled. To enable Remote Review (password required), go to the Results Configuration screen, select Remote Review, then press the Enter key to enable (On) - disable is Off.

Features of Remote Review are as follows:

- **Send Results Data to PDM for Review:** When all results and calculated parameters are available, the pHOx Series Analyzer transmits all this data to the PDM. The analysis cycle is suspended indefinitely until the PDM returns a record or the review is bypassed or cancelled.
- **Suppress Results Data:** The PDM will return a reviewed data record to the pHOx Series Analyzer. The analyzer will suppress test results based on the information received from PDM.
- **Bypass Review:** A pHOx Series operator with password level 1 or level 2 can bypass a remote review session. When the session is bypassed, the results are saved, displayed, and printed (if automatic printing is on). A reviewed data record sent by PDM is ignored if the review session is bypassed.
- **Cancel Review:** A pHOx Series operator can cancel a remote review session. When the session is cancelled, the results are saved, but the results will not be displayed or printed. A reviewed data record sent by PDM is ignored if the review session is cancelled.
- **Review Patient Name:** PDM can return a patient name with the suppressed test results. The patient name will be displayed and printed with the result data if the patient name entry feature is ON.
- **Review Patient ID:** PDM can return a patient ID with the suppressed test results. The patient ID will overwrite the existing operator ID. The patient ID will be displayed and printed with the result data.
- **Review Accession Number:** PDM can return an accession number with the suppressed test results. The accession number will overwrite the existing accession number. The accession number will be displayed and printed with the result data.

2.5 Results Suppression

In the Results Configuration screen, test results can be suppressed: will not be displayed, printed, or transmitted. The suppressed results will only affect analysis results: it will still calibrate.

Measured tests that depend on the results from a suppressed test will not be displayed. A dependency error is displayed.

Calculated parameters that depend on suppressed results are not calculated.

Suppress results as follows:

1. In the Results Configuration screen, scroll down to Results Suppression.
2. Press the Enter key to get a pop-up screen of the tests.
3. Scroll to the test that you want to suppress then press the Enter key.
4. Scroll to the next test or exit from screen.
5. On the Home screen, the suppressed test will have a strike through the test; no results will be reported on this test.

2.6 Mandatory Patient ID

In the Results Configuration screen, the Mandatory Patient ID is enabled or disabled. If enabled, the Sample Information screen will prompt for Patient ID before the sample analysis can continue.

A patient name can be sent from PDM as part of a remote review session.

A patient name can also be received from a bar code device or external keyboard through the bar code port.

2.7 Display Temperature Corrected

In the Results Configuration screen, the corrected temperature (displayed and printed) can be On or Off. If Off, only the measured temperature at 37°C is displayed and printed. But if a corrected temperature is entered when Off, both measured and corrected are displayed and printed. If On, both the measured and the corrected temperatures are displayed and printed. If no temperature is entered when On, both measured and corrected will be at 37°C.

2.8 Operation Configuration Menu

The Operation Configuration Menu screen allows you to setup the analysis output options, to configure calibration frequency, and to set date, time, barometric pressure, analyzer ID number, and to change the analysis mode (A or B); to select Hb Measured or Calculated (in analyzers that perform the test); to select the Ca^{++} or the Cl^{-} sensor (the one that is installed/ in analyzers that perform the tests); to select STAT Mode; to set Glu Membrane Test Time (in analyzers that perform the test); set the Default Panel (to override for a test, press panel and select).

2.9 QC Save Modes

The QC results are saved in one of 3 modes. The modes are Mode A, Mode B, and Mode C. To select a mode, press the QC button from the Home screen; select Setup QC (press ENTER and input password); from the QC Setup screen, select QC Save Mode; press ENTER until the mode you want is displayed.

2.9.1 Mode A

When a QC is run and a result is out of range, the QC Exceed Limits screen is displayed with the options Save, Delete, and Print. The analyzer will be locked until you Save or Delete the current results. If the Save button is pressed, only the results that are within range are saved. Any results that are out of range are discarded. If the Delete button is pressed, all results are discarded. If the Print button is pressed, the exceed limits report is printed with all reported results - pass or fail.

When the Analysis Transmit Mode is set to auto, the QC results are transmitted after you save the QC results from the QC Exceed Limits screen.

When the Analysis Print Mode is set to auto, the QC Exceed Limits printout is printed at the completion of the analysis, and the QC results are printed after you choose to save the QC results from the QC Exceed Limits screen.

2.9.2 Mode B

When a QC is run and a result is out of range, the QC Exceed Limits screen is displayed with the options Save, Delete, and Print. The analyzer will be locked until you Save or Delete the current results. If the Save button is pressed, all reported results are saved - pass or fail. If the Delete button is pressed, all results are discarded. If the Print button is pressed, the exceed limits report is printed with all reported results - pass or fail.
When the Analysis Transmit Mode is set to auto, the QC results are transmitted after you save the QC results from the QC Exceed Limits screen.
When the Analysis Print Mode is set to auto, the QC Exceed Limits printout is printed at the completion of the analysis, and the QC results are printed after you choose to save the QC results from the QC Exceed Limits screen.

2.9.3 Mode C

When a QC is run and a result is out of range, the QC Exceed Limits screen will not be displayed. All results are saved - pass or fail. The QC Results screen is displayed, and the analyzer will not be locked. For a scheduled Auto-Cartridge QC, the QC Results screen is not displayed.
When the Analysis Transmit Mode is set to auto, the QC results are automatically transmitted after the completion of the analysis.
When the Analysis Print Mode is set to auto, the QC results will automatically printed after the completion of the analysis.

2.10 Communications

The Communication screen allows you to setup the communication ports: Baud, Stop, Data, and Parity. Also, the External Keyboard and CO-Oximeter attached (Yes or No) is selected here. Finally the Bar Code Setup, select the characters for Default, Patient ID, Operator ID, and Accession #.

2.10.1 Bar Code Setup

When bar code information is scanned into the analyzer, the pHOx selects the information according to the setup options. The following options are given to select bar code information:

- Default (cannot be changed) – Characters are read from left to right starting from the first character and continuing up to the number specified by the field it was requested from.

- Patient ID Number – Any 15 characters out of the 30 can be used for the Patient ID. The default is the first 15 characters.
- Operator ID Number – Any 12 characters out of the 30 can be used for the Operator ID. The default is the first 12 characters.
- Accession Number – Any 15 characters out of the 30 can be used for the Accession Number. The default is the first 15 characters.
- All other scans will use the default setting.

Setup the Bar code characters for each option as follows:

1. Press Menu then press Setup.
2. Select Communications and press Enter; select Bar Code Setup and press Enter.
3. The highlight defaults to the Patient ID field. Use the up/down arrows to select an option to change then press Enter.
4. A character is in reverse video if it is not used for the bar code scan. The highlight is reverse of the character it is on. To change the characters, move the highlight by using the left and right arrow keys the press enter to toggle.
5. No visual effect will take place when you toggle until you move the highlight off the character that was toggled.
6. Press Exit to set new characters; press Reset to retain the default settings.

Example:

If the first 1 is off, it will appear in reverse video (black background with white character). When the highlight is moved to this character, it appears as a black character with white background. After the Enter key is pressed, the character toggled with no visual effect. Move the highlight off this character. The character appears as a black character with white background, indicating it is ON.

To test the bar code setup, go to the Bar Code Test Screen.

1. From the Ready screen, press Menu then press Service.
2. Select Communication Test then press Enter.
3. Press Scan Bar code characters then press Enter.
4. Upon entry into the screen, there is no data. To test the bar code settings, scan a bar code while this screen is displayed. All the information will be updated with the last successfully scanned bar code.

2.11 Remote Control

Remote control is enabled on the PDM side. See the PDM Manual for information. The analyzer's system ready status information is sent to the PDM upon each change of status: barometer, temperature, calibrator cartridge, control pack, minimum calibration, QC test lockout, QC level lockout, and standby mode state.

The system test status information is sent to the PDM after calibration, QC, and glucose performance cycles are completed. This test status information includes the calibration status and QC lockout status of each test and the performance status of glucose.

Remote control from the PDM can do the following:

- Initiate a 2-point calibration sequence
- Run an internal QC (any level)
- Run a glucose membrane performance test
- Turn global suppression on or off
- Enter or delete passwords
- Maintain a maintenance activity record that is sent to the PDM at the completion of the maintenance. The maintenance status information includes an operator ID, an activity ID, and the date and time of the maintenance.

2.12 Sample Number Counter

The screen allows you to check and/or to change the Sample Number Counter, but the Total Samples Accepted number, the Total Internal QC Samples Accepted number, and the Total Samples and Internal QC number are read only.

2.13 Standby Mode

This option allows you to place the analyzer into a standby mode and allows you to reactivate the analyzer at a programmed time and date. The standby mode will use less calibrators and controls because the analyzer will not run its automatic calibration cycles. Calibration is lost except for SO_2 and Hb. Standby mode ends after the set time is elapsed; if you turn Standby off; or if you initiate a calibration. The analyzer automatically performs 2 successive calibrations after Standby mode ends.

The following is the procedure to set the Standby Mode:

1. From the Operational Menu, scroll down to the Standby Mode with the Down Arrow key.
2. Press ENTER (once if OFF or twice if ON).
3. To set the date, press ENTER again - the date becomes blank.
4. Key in the date that you want the analyzer to come out of Standby Mode.
5. Press ENTER to set (DO NOT press OK).
6. Press any Arrow key to change the time. Then press ENTER - the time becomes blank.
7. Key in the time that you want the analyzer to come out of Standby Mode.
8. Press ENTER to set (DO NOT press OK).

9a. Press OK (soft key) to go into Standby Mode. Another pop-up screen appears to verify that you want to go into Standby Mode. Press OK (soft key) again. Standby Mode is now ON.

9b. Press Cancel (soft key) to cancel Standby Mode. The date and time reverts to the previous settings. The Standby Mode is now OFF.

3 Advanced Maintenance

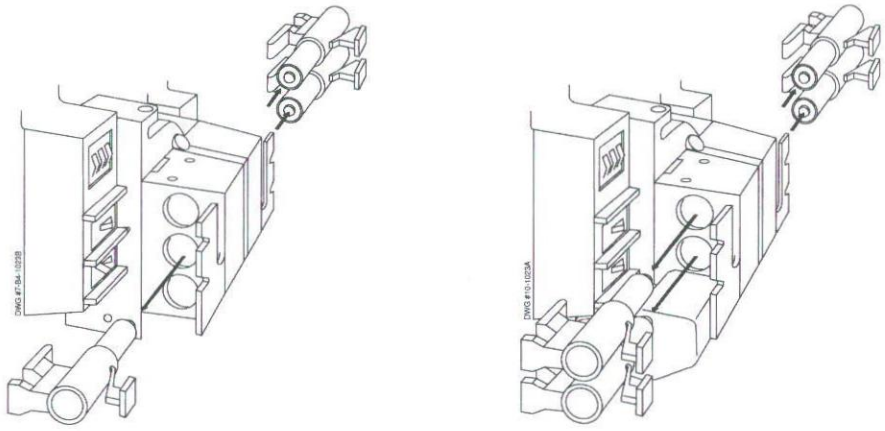
This section describes the advanced maintenance of the Stat Profile pHOx Series Analyzers. These procedures are to be done by a factory authorized representative.

3.1 Sensor Module Replacement

If the sensor module becomes damaged, replace it. Use the following procedure when you need to replace it.

pHOx Basic and pHOx

1. From the Operation Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. When the cycle is completed, **POWER DOWN THE ANALYZER**. Open the door.
3. Remove the reference sensor; the SO_2 sensor; and the air detector's sample line.
4. Press the tab on the sensors to remove them.



pHOx Basic Sensors ***pHOx Sensors***

Figure 3.1 Removing the Sensors

5. Disconnect the air detector's sample line.
6. Push the 2 locking levers to the vertical position.

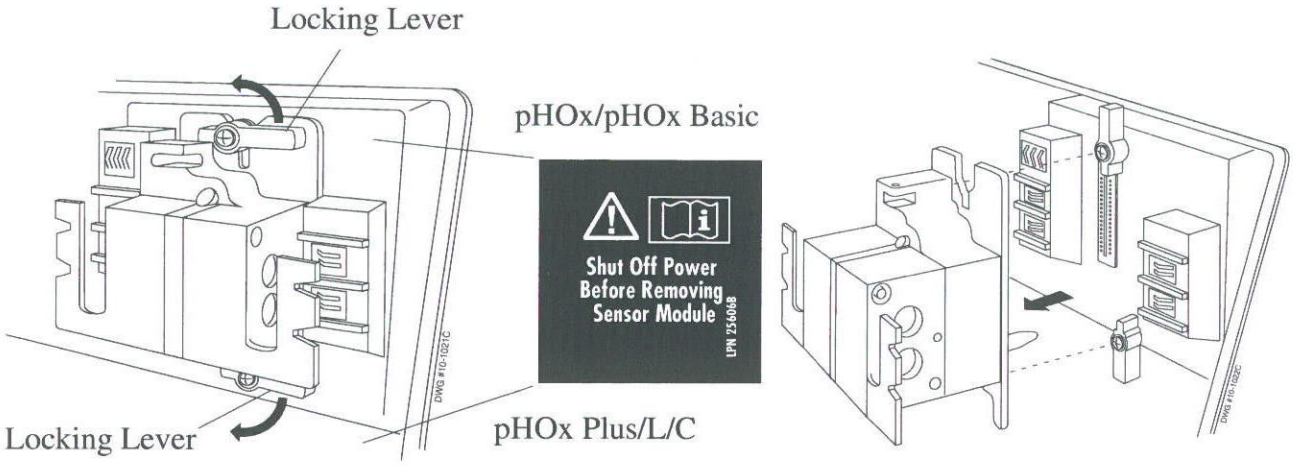


Figure 3.2 Unlocking and Removing the Sensor Module

7. Remove the sensor module; pull it straight out.
8. Guide the new sensor module into place so that it fits flat.
9. Push the 2 locking levers to the horizontal position.
10. Replace sensors back into their appropriate place in the sensor module; the sensor clicks into position.

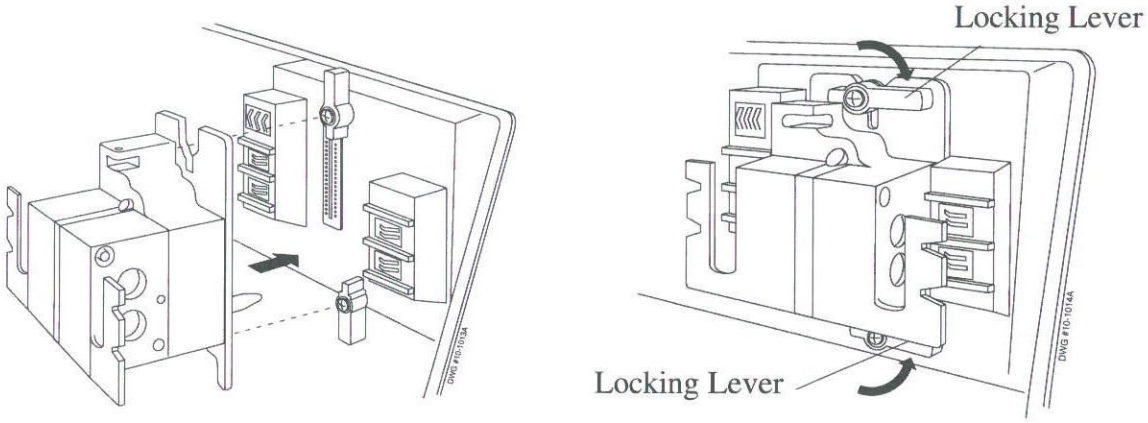
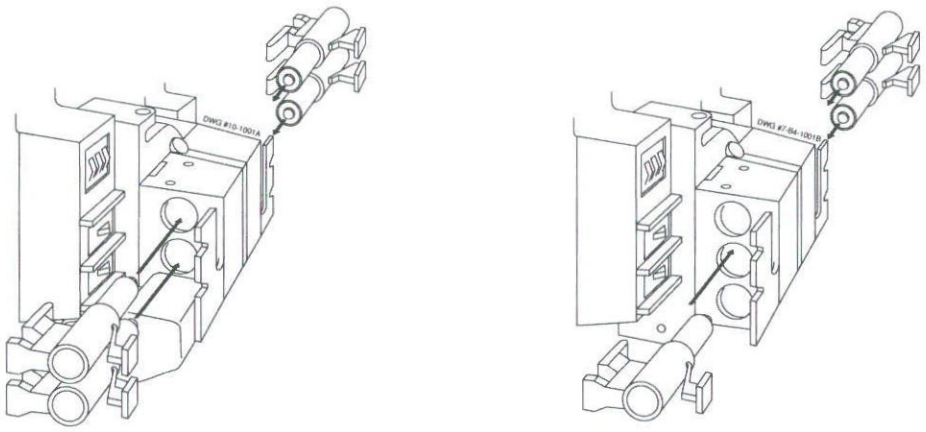


Figure 3.3 Replacing and Locking the Sensor Module



pHOx Basic Sensors ***pHOx Sensors***

Figure 3.4 Replacing the Sensors

11. Replace the reference sensor; the SO_2 sensor; and the air detector's sample line.
12. Close the door.
13. Power up the analyzer.
14. Calibrate the analyzer.

pHOx Plus, Plus C, Plus L

1. From the Operational Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. When the cycle is completed, **POWER DOWN THE ANALYZER**. Open the door.
3. Remove the reference sensor; the SO_2 sensor; and the air detector's sample line.
4. Press the tab on the sensors to remove them.

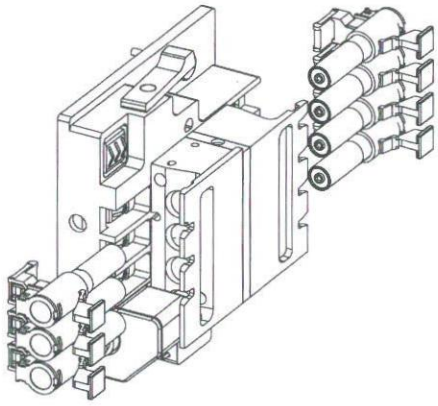


Figure 3.5 Removing the Sensors

5. Unscrew the 2 locking screws to release the module.
6. Remove the sensor module; pull it straight out.

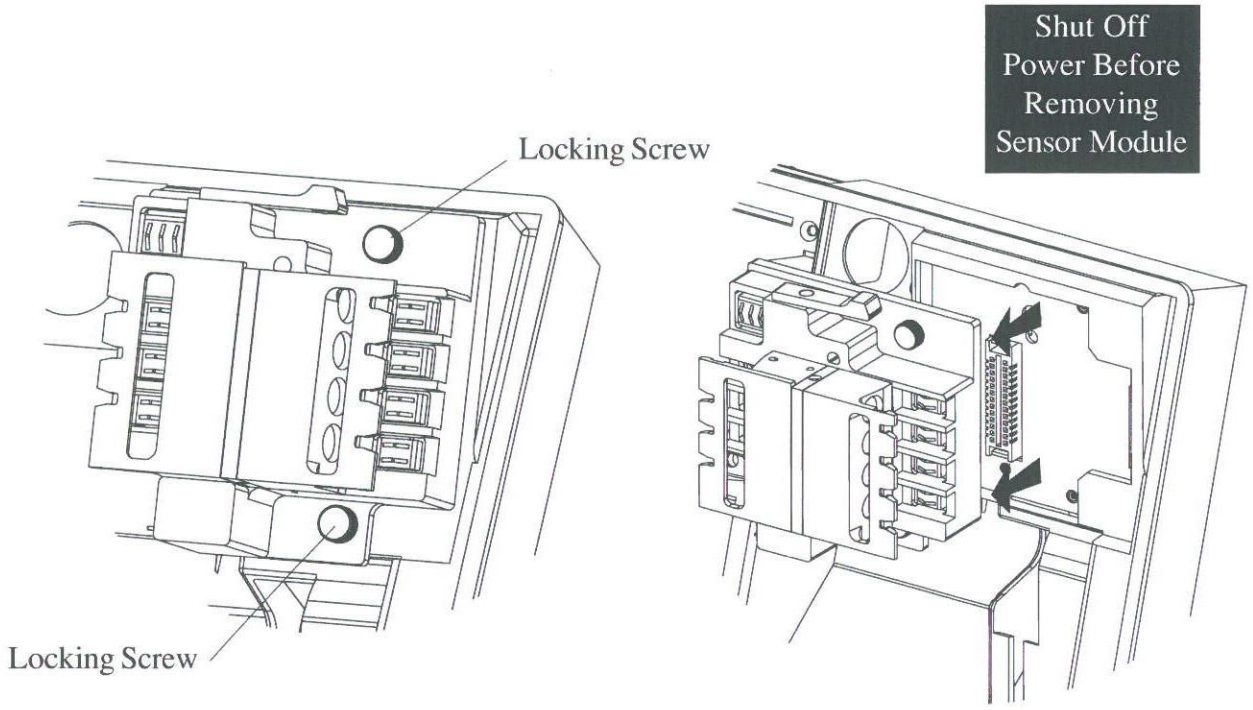


Figure 3.6 Unlocking and Removing the Sensor Module

7. Disconnect the 3 ribbon connectors. (They are labelled for reattachment.)
8. To the new sensor module attach these 3 ribbon connectors and guide the module into place so that it fits flat taking care not to pinch the ribbon connectors.
9. Screw-down the 2 locking screws.
10. Replace sensors back into their appropriate place in the sensor module; the sensor clicks into position.

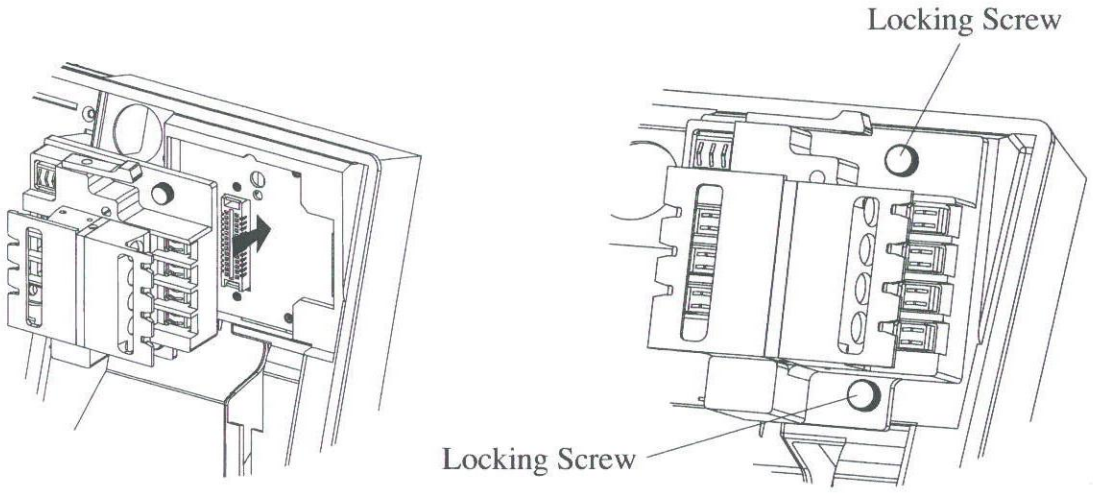


Figure 3.7 Replacing and Locking the Sensor Module

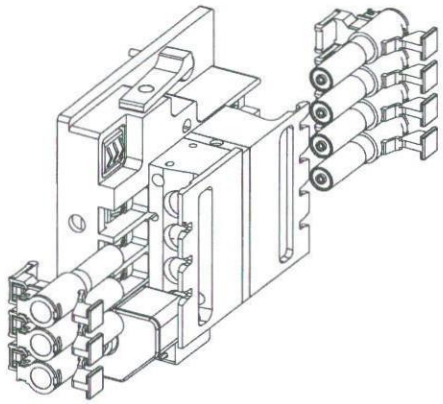


Figure 3.8 Replacing the Sensors

11. Replace the reference sensor; the SO_2 sensor; and the air detector's sample line.
12. Close the door.
13. Power up the analyzer.
14. Calibrate the analyzer.

3.2 Display/Cabinet Cleaning

Cleaning the Display: Clean the display screen with a damp (not wet) lint-free cloth. For a heavy buildup, use a liquid glass cleaner sprayed onto a lint-free cloth first, never spray directly onto the display. If available, prepackaged screen wipes can also be used.

Cleaning the Cabinet: Clean the cabinet with a damp (not wet) lint-free cloth. Do not use aerosol sprays, solvents, or abrasives that might damage the finish.

3.3 Cleaning for High Sample Throughput

The intended use of the analyzer is for a sample throughput of less than 75 samples in a 24 hour period. If running 75 or more samples per 24 hours on the analyzer, additional maintenance will better assure satisfactory performance. The following cleaning procedure should be performed on a periodic basis to insure proper operation. The frequency of this maintenance will be dictated by the actual usage of the analyzer.

1. From the Operational Menu screen, select Flowpath/Probe Maintenance and press Enter.
2. Disconnect the W-Line Tubing from the W-Reference Port.
3. Attach a syringe containing deionized water to the W-Port on the Reference Sensor.
4. Place a beaker, cup, or gauze at the tip of the sample probe.
5. Flush the deionized water in the syringe through the probe.
6. Flush air in the syringe through the probe.
7. Attach the W-Line to the W-Reference Port
8. Press CANCEL 2 times.
9. Calibrate the analyzer 2 times.

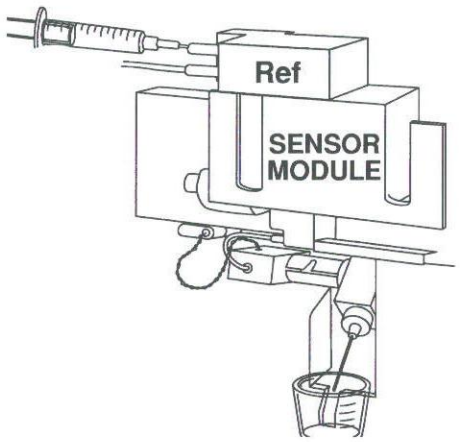


Figure 3.9 Flushing the Flowpath

3.4 Shutdown Procedure

If the analyzer is to be turned off for more than 24 hours, flush the tubing harness first with distilled water then with air. Use the Flush Fixture (PN 24327) to perform this procedure.

> **NOTE:** *If the analyzer is to be shutdown for more than 1 week, remove the sensors and rinse and dry the flow cell.*

1. Remove the Calibrator and Control Packs from the analyzer.
2. Install the Flush Fixture into the analyzer in the same way as the Calibrator Pack.
3. Place the W-line of the fixture into an empty container.
4. Place the other tubing ends into a beaker of distilled water.
5. From the Ready/Not Ready screen, press Menu (soft key).
6. Select Flowpath Maintenance and press Enter.
7. Press Purge (soft key).
8. When the cycle ends, take all the tubings out of the distilled water. Leave the W-line in its container.
9. Repeat the purge with air.
10. When this cycle is completed, remove the flush fixture.
11. Relax the pump tubing by removing one of the mounting blocks from its bracket.
12. The pHOx Plus/Plus L Analyzer is now ready to be powered off for an extended time.

4 Service Menu

To display the Service Menu, press Service (soft key) from the Operational Menu. Then enter your password. The Service Menu allows access to the following options:

- System Test
- Analog Input - Real time mV
- Sensor Subsystem (Calibration and Analysis data)
- Printer Menu
- Error Log
- Communications tests
- Versions List

4.1 Sensor Subsystem Screens

From the Service Menu, select Sensor Subsystem and press Enter. You can scroll through the sensor screens by pressing Next Screen (soft key). The following are the status screens:

- pH Sensor — Tier 1: All
- PCO_2 Sensor
- PO_2 Sensor
- Air Detectors
- SO_2 LED 1 — Tier 2: pHOx, Plus, Plus C, Plus L
- SO_2 LED 2
- Hct Sensor
- Na^+ Sensor
- K^+ Sensor — Tier 3: Plus, Plus C, Plus L
- Cl^- Sensor
- Glu Sensor
- Lac Sensor — Tier 4: Plus L

A printed record for each screen can be obtained by pressing Print (soft key). All the diagnostic information on the screen is printed (standards, slope, concentrations, etc.).

4.2 System Test

From the Service Menu, select System Test and press Enter. The System Test screen displays millivolt readings for all sensors. From the System Test screen, you can check the sampler, rotary valve, pump, waste valve, reference valve, ADT's and SO_2 LED's.

4.2.1 Running a Flow Test and Checking the Rotary Valve Operation

A flow test can be run on each calibrator. To run a flow test, display the System Test screen and select Service Flow Test (soft key), Run Test (soft key). When the test is completed, the Flow Test Results screen is displayed with the flow results for all calibrators and internal controls.

4.2.2 Checking the Sampler

The sampler can be in any one of several positions: capillary, syringe, air, or home. These positions can be manually checked by selecting the Sampler option on the System Test screen.

1. Select Sampler with arrow keys.
2. Press Enter.
3. A pop-up window is displayed over the screen. Using the arrow keys, select a sampler position.
4. After the sampler travels to the selected position, check that the sampler is positioned correctly.

4.2.3 Checking the Pump

There are 4 pump speeds: slow, medium slow, medium fast, and fast. These speeds can be manually checked by selecting the Pump option on the System Test screen.

1. Select Pump with arrow keys.
2. Press Enter.
3. A pop-up window is displayed over the screen. Select one of the 4 pump speeds with the arrow keys. Then press Enter to activate the pump.
4. Check that the pump is working and pumping fluid.
5. To stop the pump, repeat steps 1 thru 3 and select the stop option with the arrow keys. Then press Enter to stop the pump.

4.2.4 Checking the Waste Valve

The waste valve can be checked by selecting Waste valve with the arrow keys on the System Test screen. Press Enter to open or close the valve.

4.2.5 Checking the Reference Valve

The reference valve can be checked by selecting Ref. valve with the arrow keys on the System Test screen. Press Enter to open or close the valve.

4.2.6 Checking the SO_2 LEDs

(pHOx, pHOx Plus, Plus C, Plus L)
From the System Test screen press Next Page (soft key). The SO_2 LEDs can be checked by selecting SO_2 LEDs with the arrow keys on the second System Test screen. Press Enter to turn the lights on or off.

4.2.7 Checking the Air Detectors

The air detectors can be checked by setting the X-level of the air detector of interest and then enabling the air oscillator. From the System Test screen, press Next Page (soft key), select X-level with the arrow keys, then press Enter. Select the desired air detector then press Enter. Select the air oscillator with the arrow keys then press Enter to turn the detector on or off.

4.3 Analog Input

From the Service Menu, select the Analog Input option and press Enter. The Analog Input screen is displayed with the 25 channels and the millivolt readings.

4.4 Printer Menu

From the Service Menu, select the Printer Menu option and press Enter. The Printer Menu screen is displayed with 4 options: Printer Enabled, Print System Error Log, Print System Dump, or Character Set Test.

1. Select an option with the arrow keys.
2. Press Enter.
   - Printer Enabled or Disabled, press enter to enable or disable the printer.
   - Print System Error Log, press Enter to print the error logs for the analyzer.
   - Print System Report, press Enter to print all the setup, calibration, and analysis data.
   - Character Set Test, press Enter to print all characters test pattern of the printer.
   - Print Operator Passwords, press Enter to print the operator passwords.
3. Press Exit (soft key) to return to the Service Menu.

4.5 Error Log

From the Service Menu, select the Error Log option and press Enter. The Error Log screen is displayed with errors displayed in chronological order. To go to the next or previous error log pages, press the Page Down or Page Up (soft keys). To print the error log, select Printer Menu from the Service Menu.

4.6 Communications Test

From the Service Menu, select the Communications Test option and press Enter. The Communications Tests screen is displayed with the 2 options: Loopback Tests and Send test characters.

LoopBack Test

1. Select the Loopback Tests option on the Communications Tests screen.
2. Press Enter to display the Loopback Tests screen.
3. Use the arrow keys to select a port: Bar Code, Computer, and COOX.
4. Install the loopback plug.
5. Press Enter to start the test.

Send Test Characters

1. Select the Send Test Characters option on the Communications Tests screen.
2. Press Enter to display the Send Test Characters screen.
3. Use the arrow keys to select a port: Bar Code, Computer, and COOX.
4. Press Send Characters (soft key) to send the character packet.

4.7 RS-232 Serial Ports

The Stat Profile pHOx Series Analyzers' communications interface is an asynchronous RS-232C compatible serial interface. The analyzer can transfer analytical results to an external device (CO-Oximeter, PDM, computer, etc.). There are 3 serial communication ports and 1 bar code reader port located at the back of the analyzer. Each port uses a standard DB9P male connector to connect the analyzer to external devices. Table 4.1 describes the layout of the pHOx Plus/Plus L's 9-pin connectors, and Table 4.2 assigns the connections.

Table 4.1 External Device 9-pin Connector

Pin Assignment	Signal Designation	Circuit Source	Function
1	RCD	EXTERNAL	Data Carrier Detect
2	RXD	EXTERNAL	Received data
3	TXD	ANALYZER	Transmitted data
4	DTR	ANALYZER	Data Terminal Ready
5	GND	-	Signal Ground
6	DSR	EXTERNAL	Data Set Ready
7	RTS	ANALYZER	Request to Send
8	CTS	EXTERNAL	Clear to Send
9	RI	EXTERNAL	Ring Indicator

Table 4.2 Serial Port and Device Connections

Serial Port	Device
Bar Code Port	Bar Code Scanner/External Keyboard
COM 1	Nova's use only
COM 2	PDM/Computer
COM 3	CO-Oximeter

The analyzer can transmit or receive data at any one of 3 bauds: 4800, 9600, and 19200. Word length is fixed at 7 or 8 bits. Configure the ports from the Setup Menu. The following are the setup options with the defaults in bold:

Baud	4800, **9600**, 19200
Stop Bits	**1** or 2
Parity	**None**, Odd, Even
Data Bits	7, **8**

4.7.1 CO-Oximeter Interface

The Stat Profile pHOx Series Analyzers can interface with the Nova CO-OXIMETER via the serial communications port (COM 3) to receive CO-Ox results.

4.7.2 PDM/Computer Interface

The Stat Profile pHOx Series Analyzers can interface with the Nova PDM or an external computer via the serial communications port (COM 2) to transmit patient results. See Section 7.

4.7.3 Bar Code Scanner Port

An optional bar code scanner can be connected to the Stat Profile pHOx Series Analyzers to input patient data. The patient information can be programmed onto a bar code sticker that is attached to the patient's sample. Then the patient's information can be easily inputted via the bar code scanner into the analyzer.

Follow this procedure to set up the bar code scanner.

1. Calibrate the analyzer if it is not calibrated.
2. Plug the bar code scanner into the Bar Code Scanner Port (DB-9P) on the back of the analyzer.
3. Listen for a tone. This indicates that the bar code is ready.
4. Start a sample analysis.
5. When the Sample Information screen is displayed, scan in the following as needed:
   - Accession number
   - Patient ID number (English only, alphanumeric)
   - Operator ID
   - Patient Temperature
   - Patient Name (if enabled)
6. Continue the analysis.

4.7.4 External Keyboard

Follow the directions of the insert sheet that comes with the keyboard.

5 Communications

This document describes how the Nova pHOx Series transmits data to an external computer. Data transmission involves a low-level protocol and a high-level protocol. The low-level protocol is concerned with establishing communication, detecting errors, and sending and receiving messages. It is not concerned with message content. The high-level protocol is concerned with message content.

The protocols used are designed to conform to specifications published by the American Society for Testing and Materials (ASTM). Copies of the specifications can be obtained by contacting ASTM:

ASTM
100 Barr Harbor Drive
West Conshohocken, PA 19428-2959
USA
phone: 610-832-9585
FAX: 610-832-9555

The low-level protocol used by the Nova pHOx Series Analyzers are designed to conform to **ASTM E1381-91**. This document is concerned with the high level protocol only.

The following information pertains to pHOx Series only samples, pHOx Series only calibration, pHOx Series only QC, and Combined results.

The pHOx Series also transmits COOX only data. Those records are specified by the COOX ASTM specification.

5.1 High-Level Protocol

The high-level protocol used by pHOx Series Analyzers are designed to conform to **ASTM E1394-91**.

The tables that follow describe the data records that are sent by pHOx Series Analyzers. The column "ASTM REF" lists the section of the ASTM E1394-91 specification that defines the field. The column "ASTM NAME" lists the field name that appears in the ASTM specification.

Unless otherwise noted, any field that involves date and time conforms to section 6.6.2 of ASTM 1394-91. Each record ends with a carriage return.

5.1.1 Header Record

ASTM REF	ASTM NAME	pHOx Series IMPLEMENTATION
7.1.1	Record Type ID	Single character: "H"
7.1.2	Delimiter Definition	Standard delimiters: |\^&
7.1.3	Message Control ID	*Not Used*
7.1.4	Access Password	*Not used*
7.1.5	Sender Name or ID	NOVA^pHOx Plus^vv..vv^dd Where 'vv..vv' is the version of pHOx Series software, and 'dd' is Analyzer Identification # set by the pHOx Series operator.
7.1.6	Sender Street Address	*Not used*
7.1.7	Reserved Field	*Not used*
7.1.8	Sender Telephone Number	*Not used*
7.1.9	Characteristics of Sender	*Not used*
7.1.10	Receiver ID	*Not used*
7.1.11	Comment or Special Instruction	*Not used*
7.1.12	Processing ID	*Not used*
7.1.13	Version No.	Version of ASTM Spec., single char.: "1"
7.1.14	Date and Time of Message	Date and time at which message was transmitted. (This is not the time of the analysis or calibration.)

5.1.2 Patient Information Record

ASTM REF	ASTM NAME	pHOx Series IMPLEMENTATION
8.1.1	Record Type	Single character: "P"
8.1.2	Sequence Number	Single character: "1." (This will always be "1" because there will be only one patient record per message.) **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
8.1.3	Practice Assigned Patient ID	*Not used*
8.1.4	Laboratory Assigned Patient ID	Patient ID # if available; otherwise, blank. For patient samples, Patient ID # is available if and only if it was entered by the pHOx Series operator. For QC samples and for calibrations, this will be blank. **NOTE:** This is the last field that is used in this record.
8.1.5	Patient ID No. 3	*Not used*
8.1.6	Patient Name	Last^ First^ Middle
8.1.7	Mother's Maiden Name	*Not used*
8.1.8	Birthdate	*Not used*
8.1.9	Patient Sex	*Not used*
8.1.10	Patient Race-Ethnic Origin	*Not used*
8.1.11	Patient Address	*Not used*
8.1.12	Reserved Field	*Not used*
8.1.13	Patient Telephone Number	*Not used*
8.1.14	Attending Physician ID	*Not used*
8.1.15	Special Field 1	*Not used*

8.1.16	Special Field 2	*Not used*
8.1.17	Patient Height	*Not used*
8.1.18	Patient Weight	*Not used*
8.1.19	Patient's Known or Suspected Diagnosis	*Not used*
8.1.20	Patient Active Medications	*Not used*
8.1.21	Patient's Diet	*Not used*
8.1.22	Practice Field No. 1	*Not used*
8.1.23	Practice Field No. 2	*Not used*
8.1.24	Admission and Discharge Dates	*Not used*
8.1.25	Admission Status	*Not used*
8.1.26	Location	*Not used*
8.1.27	Nature of Alternative Diagnostic Code and Classifiers	*Not used*
8.1.28	Alternative Diagnostic Code and Classification	*Not used*
8.1.29	Patient Religion	*Not used*
8.1.30	Marital Status	*Not used*
8.1.31	Isolation Status	*Not used*
8.1.32	Language	*Not used*
8.1.33	Hospital Service	*Not used*
8.1.34	Hospital Institution	*Not used*
8.1.35	Dosage Category	*Not used*

5.1.3 Test Order Record

ASTM REF	ASTM NAME	pHOx Series IMPLEMENTATION
9.4.1	Record Type ID	Single character: "O"
9.4.2	Sequence Number	Single character: "1." (This will always be "1" because Ultra will send only one order per message.) **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
9.4.3	Specimen ID	For patient samples, accession # if available; otherwise, blank. For QC analyses, the ID is one of the following: "QC0 Proficiency" "QC1 Level 1 Internal" "QC2 Level 2 Internal" "QC3 Level 3 Internal" "QC4 Level 1 External" "QC5 Level 2 External" "QC6 Level 3 External" "QC7 Level 4 External" "QC8 Level 5 External" For calibrations, this field is blank.
9.4.4	Instrument Specimen ID	Sample Number from pHOx's Sample Number Counter.
9.4.5	Universal Test ID	*Not used*
9.4.6	Priority	*Not used*
9.4.7	Requested/Ordered Date and Time	*Not used*
9.4.8	Specimen Collection Date and Time	*Not used*
9.4.9	Collection End Time	*Not used*
9.4.10	Collection Volume	*Not used*
9.4.11	Collector ID	*Not used*

9.4.12	Action Code	*Not used*
9.4.13	Danger Code	*Not used*
9.4.14	Relevant Clinical Information	*Not used*
9.4.15	Date/Time Specimen Received	*Not used*
9.4.16	Specimen Descriptor	For patient samples, this will be the sample type ("Arterial," "Venous," "Capillary," or "Mixed Venous"). For QC samples, this will be "Control." For calibrations, this will be "Cal."
9.4.17	Ordering Physician	*Not used*
9.4.18	Physician's Telephone Number	*Not used*
9.4.19	User Field No. 1	*Not used*
9.4.20	User Field No. 2	*Not used*
9.4.21	Laboratory Filed No. 1	*Not used*
9.4.22	Laboratory Filed No. 2	*Not used*
9.4.23	Day/Time Results Reported or Last Modified	*Not used*
9.4.24	Instrument Charge to Computer System	*Not used*
9.4.25	Instrument Section ID	*Not used*
9.4.26	Report Types	'F' - final results (Results do not require remote review.) 'P' - remote review
9.4.27	Reserved Field	*Not used*
9.4.28	Location or Ward of Specimen Collection	*Not used*
9.4.29	Nosocomial Infection Flag	*Not used*

9.4.30	Specimen Service	*Not used*
9.4.31	Specimen Institution	*Not used*

5.1.4 Result Record

ASTM REF	ASTM NAME	pHOx Series IMPLEMENTATION
10.1.1	Record Type	Single character: "R"
10.1.2	Sequence Number	Counts the parameters sent for this order; '1' for the first parameter, '2' for the second, etc. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
10.1.3	Universal Test ID	Four or five components; the first three are not used (see sections 6.6.1.1-6.6.1.3 of ASTM E1394-91). The fourth is a parameter name assigned by NOVA. The fifth, if present, will be the parameter type; it will be one of the following: C - Calculated D - Default E - Entered M - Measured T - Temperature Corrected **NOTE:** Parameter names are listed elsewhere in this document.
10.1.4	Data or Measurement Value	Value of the parameter as an ASCII string.
10.1.5	Units	Abbreviation of units.
10.1.6	Reference Ranges	*Not used*

10.1.7	Result Abnormal Flags	HH - Above High Panic value H - Above High Reference value L -Below Low Reference value LL - Below Low Panic value > - Above the range of the analyzer < - Below the range of the analyzer When calibration data is sent, this field will be one of the following: A - (abnormal) channel is not calibrated N - (normal) channel is calibrated **NOTE:** When this field is blank, at least one of the following is true: a. A reference range has been set, and the measurement is within the reference range. b. A reference range has not been set, but a panic range has been set, and the measurement is within the panic range. c. Neither a reference range nor a panic range has been set. d. The sample is a Q.C. sample.
10.1.8	Nature of Abnormality Testing	*Not used*
10.1.9	Result Status	'F' - final results (Results do not require remote review.) 'P' - remote review
10.1.10	Date of Change of Instrument Normative Values or Units	*Not used*
10.1.11	Operator Identification	Operator ID#
10.1.12	Date/Time Test Started	Date&time at which the analysis or cal. started.
10.1.13	Date/Time Test Completed	*Not used*
10.1.14	Instrument Identification	pHOx Series Analyzers ID.

5.1.5 Comment Record

Comment Record(s) will immediately follow a Test Order if and only if there were any errors during sample analysis. There will be one Comment Record for each error.

ASTM REF	ASTM NAME	pHOx Series IMPLEMENTATION
11.1.1	Record Type	Single character: "C"
11.1.2	Sequence Number	Counts the comments sent for this order; '1' for the first comment, '2' for the second, etc. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
11.1.3	Comment Source	Single character: "I"
11.1.4	Comment Text	An error code followed by descriptive text. (e.g., "25 Na Unstable").
11.1.5	Comment Type	Single character: "I"

5.1.6 Message Terminator Record

ASTM REF	ASTM NAME	pHOx Series IMPLEMENTATION
13.1.1	Record Type	Single character: "L"
13.1.2	Sequence Number	For this record type this is always "1." **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
13.1.3	Termination Code	One of the following: N - normal termination T - sender aborted

5.1.7 Parameter Names

The parameter names listed here are used as *Manufacturer's or Local Code* (see ASTM E1394-91 sec. 6.6.1.4). They are used to create the Universal Test ID field of the result record (see Result Record above and see ASTM E1394-91 sec. 10.1.3).
In most cases only a subset of these parameters will be transmitted. For example, during setup of the pHOx Series Analyzer, the operator can disable transmission of any or all of the following:

- Analysis diagnostic data
- Calibration diagnostic data
- Calibration drift data

Parameter Name	Units	Description
Na+	mmol/L	Sodium Concentration
Na+_SM	mV	Sodium Sample Millivolts
Na+_M1	mV	Sodium Millivolts #1
Na+_M2	mV	Sodium Millivolts #2
Na+_M4	mV	Sodium Millivolts #4
Na+_SL	*None*	Sodium Slope
Na+_V1	*None*	Sodium Calibration Std. Value #1
Na+_V2	*None*	Sodium Calibration Std. Value #2
Hct	%	Hematocrit Concentration
Hct_SM	mV	Hematocrit Sample Millivolts
Hct_M1	mV	Hematocrit Millivolts #1
Hct_M2	mV	Hematocrit Millivolts #2
Hct_M4	mV	Hematocrit Millivolts #4
Hct_SL	*None*	Hematocrit Slope

pH	*None*	pH Concentration
pH_SM	mV	pH Sample Millivolts
pHTC	*None*	pH Conc. Corrected to Patient Temperature
pH_M1	mV	pH Millivolts #1
pH_M2	mV	pH Millivolts #2
pH_M3	mV	pH Millivolts #3
pH_M4	mV	pH Millivolts #4
pH_SL	*None*	pH Slope
pH_D1	*None*	pH Drift #1
pH_D2	*None*	pH Drift #2
pH_V1	*None*	pH Calibration Std. Value #1
pH_V2	*None*	pH Calibration Std. Value #2
PO2	mmHg, kPa	PO_2 Concentration
PO2TC	mmHg, kPa	PO_2 Conc. Corrected to Patient Temperature
PO2_SM	mV	PO_2 Sample Millivolts
PO2_M1	mV	PO_2 Millivolts #1
PO2_M2	mV	PO_2 Millivolts #2
PO2_M3	mV	PO_2 Millivolts #3
PO2_SL	*None*	PO_2 Slope
PO2_D1	*None*	PO_2 Drift #1
PO2_V1	*None*	PO_2 Calibration. Gas Value #1

PO2_V2	*None*	PO_2 Calibration. Gas Value #2
PCO2	mmHg, kPa	PCO_2 Concentration
PCO2_SM	mV	PCO_2 Sample Millivolts
PCO2TC	mmHg, kPa	Corrected PCO_2 Concentration
PCO2_M1	mV	PCO_2 Millivolts #1
PCO2_M2	mV	PCO_2 Millivolts #2
PCO2_SL	*None*	PCO_2 Slope
PCO2_D1	*None*	PCO_2 Drift #1
PCO2_D2	*None*	PCO_2 Drift #2
PCO2_V1	*None*	PCO_2 Calibration. Gas Value #1
PCO2_V2	*None*	PCO_2 Calibration. Gas Value #2
K	mmol/L	Potassium Concentration
K _SM	mV	Potassium Sample Millivolts
K _M1	mV	Potassium Millivolts #1
K _M2	mV	Potassium Millivolts #2
K _M4	mV	Potassium Millivolts #4
K _SL	*None*	Potassium Slope
K _V1	*None*	Potassium Calibration Std. Value #1
K _V2	*None*	Potassium Calibration Std. Value #2
Ca++	mmol/L	Calcium Concentration
Ca++_SM	mV	Calcium Sample Millivolts

Ca++ _M1	mV	Calcium Millivolts #1
Ca++ _M2	mV	Calcium Millivolts #2
Ca++ _M4	mV	Calcium Millivolts #4
Ca++ _SL	*None*	Calcium Slope
Ca++ _V1	*None*	Calcium Calibration Std. Value #1
Ca++ _V2	*None*	Calcium Calibration Std. Value #2
Cl-	mmol/L	Chloride Concentration
Cl- _SM	mV	Chloride Sample Millivolts
Cl- _M1	mV	Chloride Millivolts #1
Cl- _M2	mV	Chloride Millivolts #2
Cl- _M4	mV	Chloride Millivolts #4
Cl- _SL	*None*	Chloride Slope
Cl- _V1	*None*	Chloride Calibration Std. Value #1
Cl- _V2	*None*	Chloride Calibration Std. Value #2
Glu	mg/dL	Glucose Concentration
Glu _SM	mV	Glucose Sample Millivolts
Glu _M1	mV	Glucose Millivolts #1
Glu _M2	mV	Glucose Millivolts #2
Glu _M4	mV	Glucose Millivolts #4
Glu _SL	*None*	Glucose Slope
Glu _V1	*None*	Glucose Calibration Std. Value #1

Glu _V2	*None*	Glucose Calibration Std. Value #2
SO2%	*None*	SO_2 Percent
S1_SL	*None*	SO_2 LED #1 Slope
S2_SL	*None*	SO_2 LED #2 Slope
S1_SM	mV	SO_2 LED #1 Sample Millivolts
S2_SM	mV	SO_2 LED #2 Sample Millivolts
S1_M1	mV	SO_2 LED #1 millivolts #1
S1_M2	mV	SO_2 LED #1 millivolts #2
S1_M3	mV	SO_2 LED #1 millivolts #3
S1_M4	mV	SO_2 LED #1 millivolts #4
S2_M1	mV	SO_2 LED #2 millivolts #1
S2_M2	mV	SO_2 LED #2 millivolts #2
S2_M3	mV	SO_2 LED #2 millivolts #3
S2_M4	mV	SO_2 LED #2 millivolts #4
FIO2	%	Percent Fraction Inspired Oxygen
BP	mmHg	Barometric Pressure
TempM	deg C, deg F	Measurement Temperature
TempP	deg C, deg F	Patient Temperature
Hb	g/dL	Hemoglobin
Hb_SL	*None*	Hemoglobin Slope
BE-ecf	mmol/L	Base Excess, Extra-Cellular Fluid

BE-b	mmol/L	Base Excess, Blood
SBC	mmol/L	Standard Bicarbonate
HCO3-	mmol/L	Bicarbonate Ion Concentration
TCO2	mmol/L	Total CO_2
O2Ct	Vol/100mL, mL/dL, mL/L	Oxygen Content
A	mmHg,kPa	Alveolar Air PO_2
a/A	*None*	Alveolar Ratio
AaDO2	mmHg,kPa	Alveolar Arterial Oxygen Gradient
P50	mmHg	PO_2 @ 50% SO_2
O2CAP	Vol/100mL, mL/dL, mL/L	Oxygen Capacity
nCa	mmol/L, mg/dL	Normalized Calcium
Anion Gap	mmol/L	Anion Gap
RI	*None*	Respiratory Index
THb	g/dL, g/L, mmol/L	Total Hemoglobin
O2Hb	% or *None*	Oxyhemoglobin
COHb	%or *None*	Carboxyhemoglobin
MetHb	%or *None*	Methemoglobin
HHb	%or *None*	Reduced Hemoglobin
FO2Hb	% or *None*	Fractional Hemoglobin
PO2/FIO2	mmHg, kPa	
CcO2	mL/dL	capillary oxygen concentration

CvO2	mL/dL	venous oxygen concentration
CaO2	mL/dL	arterial oxygen concentration
AvDO2	mmHg, kPa	arterial-mixed venous oxygen gradient
Qsp/Qt	*None*	physiologic shunt
MTHB	g/dL	Measured tHb for a pHOx Plus/C/L Calibration
TTHB	g/dL	Target tHb for a pHOx Plus/C/L Calibration
DTHB	g/dL	tHb drift for a pHOx Plus/C/L Calibration
puncture_site	None	Entered by user
ventilator_rate/min	None	Entered by user
tidal_volume	None	Entered by user
peep_cpap	None	Entered by user
mode_of_therapy	None	Entered by user

The following are for CO-Ox diagnostics only and will not normally be transmitted:

NumScans_X	*None*
SHb_X	*None*
Turbid_X	*None*
Abs1_X	*None*
Abs2_X	*None*
Abs3_X	*None*
Abs4_X	*None*
Abs5_X	*None*

Abs6_X	*None*
Abs7_X	*None*
Abs8_X	*None*
WL1_X	*None*
WL2_X	*None*
WL3_X	*None*
WL4_X	*None*
WL5_X	*None*
WL6_X	*None*
WL7_X	*None*
WL8_X	*None*
tHbCal_X	*None*
MO2HB_X	% or *None*
TO2HB_X	% or *None*
DO2HB_X	% or *None*
MHHB_X	% or *None*
THHB_X	% or *None*
DHHB_X	% or *None*

5.2 Examples

The following examples do not include any special characters such as ENQ and STX. Also, each line ends before the checksum.

5.2.1 pHOx Series Only Patient Sample

```
1H|\^&|||NOVA^pHOx Plus^I00.05^12343210|||||||1|20000127112100F4
2P|1||123CD
3O|1|12|1008||||||||||||Arterial|||||||||F85
4C|1|I|35  SO2% Dependency|IFA
5C|2|I|45  Hb Dependency|IAE
6R|1|^^^pH^M|7.262|||||F||97|20000127111700||123432108D
7R|2|^^^PCO2^M|70.0|mmHg||||F||97|20000127111700||123432103A
0R|3|^^^PO2^M|64.5|mmHg||||F||97|20000127111700||12343210F9
1R|4|^^^Hb^M||mmol/L||||F||97|20000127111700||12343210AE
2R|5|^^^Hct^M||%||<||F||97|20000127111700||1234321056
3R|6|^^^Na+^M|172.5|mmol/L||||F||97|20000127111700||12343210DF
4R|7|^^^K^M||mmol/L||<||F||97|20000127111700||1234321091
5R|8|^^^Ca++^M|0.93|mmol/L||||F||97|20000127111700||12343210D0
6R|9|^^^Glu^M|84|mg/dL||||F||97|20000127111700||1234321025
7R|10|^^^HCO3-^C|31.9|mmol/L||||F||97|20000127111700||1234321032
0R|11|^^^BE-b^C|3.2|mmol/L||||F||97|20000127111700||12343210D0
1R|12|^^^BE-ecf^C|4.6|mmol/L||||F||97|20000127111700||12343210A3
2R|13|^^^TCO2^C|34.0|mmol/L||||F||97|20000127111700||1234321008
3R|14|^^^SBC^C|27.0|mmol/L||||F||97|20000127111700||12343210CC
4R|15|^^^A^C|67.9|mmHg||||F||97|20000127111700||123432109D
5R|16|^^^AaDO2^C|3.5|mmHg||||F||97|20000127111700||1234321087
6R|17|^^^a/A^C|0.9|||||F||97|20000127111700||123432106B
7R|18|^^^RI^C|0.1|||||F||97|20000127111700||123432102F
0R|19|^^^SO2%^C|87.7|||||F||97|20000127111700||12343210CC
1R|20|^^^nCa++^C|0.78|mmol/L||||F||97|20000127111700||123432105D
2R|21|^^^TempP^D|98.6|deg F||||F||97|20000127111700||123432104C
3R|22|^^^BP^M|756.9|mmHg||||F||97|20000127111700||123432102A
4R|23|^^^TempM^M|98.5|deg F||||F||97|20000127111700||1234321055
5R|24|^^^FIO2^D|20.9|%||||F||97|20000127111700||12343210FF
6R|25|^^^pH_SM^M|33.23|||||F||97|20000127111700||12343210BC
7R|26|^^^PCO2_SM^M|-39.56|||||F||97|20000127111700||1234321053
0R|27|^^^PO2_SM^M|-86.18|||||F||97|20000127111700||123432100A
1R|28|^^^Hct_SM^M|2366.02|||||F||97|20000127111700||1234321089
2R|29|^^^Na+_SM^M|50.15|||||F||97|20000127111700||12343210DE
3R|30|^^^K_SM^M|180.21|||||F||97|20000127111700||1234321079
```

```
4R|31|^^^Ca++_SM^M|68.73|||||F||97|20000127111700||1234321006
5R|32|^^^Cl-_SM^M|||||F||97|20000127111700||12343210E4
6R|33|^^^Glu_SM^M|27.97|||||F||97|20000127111700||1234321039
7R|34|^^^pH_M1^M|21.98|||||F||97|20000127111700||12343210A4
0R|35|^^^PCO2_M1^M|-56.80|||||F||97|20000127111700||1234321026
1R|36|^^^PO2_M1^M|-214.13|||||F||97|20000127111700||123432100D
2R|37|^^^Hct_M1^M|1963.02|||||F||97|20000127111700||123432106A
3R|38|^^^Na+_M1^M|45.80|||||F||97|20000127111700||12343210C3
4R|39|^^^K_M1^M|175.14|||||F||97|20000127111700||1234321067
5R|40|^^^Ca++_M1^M|72.21|||||F||97|20000127111700||12343210D9
6R|41|^^^Cl-_M1^M|||||F||97|20000127111700||12343210C3
7R|42|^^^Glu_M1^M|19.49|||||F||97|20000127111700||1234321016
0R|43|^^^pH_SL^M|9.58|||||F||97|20000127111700||1234321090
1R|44|^^^PCO2_SL^M|9.23|||||F||97|20000127111700||12343210E6
2R|45|^^^PO2_SL^M|-12.60|||||F||97|20000127111700||12343210FD
3R|46|^^^Hb_SL^M|10.00|||||F||97|20000127111700||12343210A3
4R|47|^^^Hct_SL^M|31.86|||||F||97|20000127111700||123432102B
5R|48|^^^Na+_SL^M|9.05|||||F||97|20000127111700||12343210B4
6R|49|^^^K_SL^M|-0.14|||||F||97|20000127111700||123432104B
7R|50|^^^Ca++_SL^M|32.90|||||F||97|20000127111700||12343210FF
0R|51|^^^Cl-_SL^M|||||F||97|20000127111700||12343210DF
1R|52|^^^Glu_SL^M|19.19|||||F||97|20000127111700||123432102F
2R|53|^^^S1_SM^M|58.54|||||F||97|20000127111700||1234321090
3R|54|^^^S2_SM^M|212.01|||||F||97|20000127111700||12343210B3
4R|55|^^^S1_M1^M|58.44|||||F||97|20000127111700||1234321071
5R|56|^^^S2_M1^M|211.84|||||F||97|20000127111700||123432109F
6R|57|^^^S1_SL^M|8.56|||||F||97|20000127111700||1234321064
7R|58|^^^S2_SL^M|10.03|||||F||97|20000127111700||1234321088
0L|1|N03
```


5.2.2 pHOx Series Only QC Sample

```
1H|\^&|||NOVA^pHOx^I00.53^123|||||||1|19980827180000
2P|1||123456
3O|1|QC4 Level 1 External|0||||||||||Control|||||||||F
4C|1|I|35  SO2% Dependency|I
5C|2|I|45  Hb Dependency|I
6R|1|^^^H+^M|70.479|nmol/L||||F||1|19980827175800||123
7R|2|^^^PCO2^M|59.8|mmHg||||F||1|19980827175800||123
0R|3|^^^PO2^M|62.3|mmHg||||F||1|19980827175800||123
1R|4|^^^Hb^M||g/dL||||F||1|19980827175800||123
2R|5|^^^Hct^M||%||<||F||1|19980827175800||123
3R|6|^^^SO2%^M|||||F||1|19980827175800||123
4R|7|^^^Na+^M||mmol/L||||F||1|19980827175800||123
```

```
5R|8|^^^pH_SM^M|43.290|||||F||1|19980827175800||123
6R|9|^^^PCO2_SM^M|102.995|||||F||1|19980827175800||123
7R|10|^^^PO2_SM^M|-42.850|||||F||1|19980827175800||123
0R|11|^^^Hct_SM^M|2243.885|||||F||1|19980827175800||123
1R|12|^^^Na+_SM^M||||||F||1|19980827175800||123
2R|13|^^^pH_M1^M|28.478|||||F||1|19980827175800||123
3R|14|^^^PCO2_M1^M|88.510|||||F||1|19980827175800||123
4R|15|^^^PO2_M1^M|-115.677|||||F||1|19980827175800||123
5R|16|^^^Hct_M1^M|1897.903|||||F||1|19980827175800||123
6R|17|^^^Na+_M1^M|66.348|||||F||1|19980827175800||123
7R|18|^^^pH_SL^M|10.584|||||F||1|19980827175800||123
0R|19|^^^PCO2_SL^M|10.389|||||F||1|19980827175800||123
1R|20|^^^PO2_SL^M|-6.731|||||F||1|19980827175800||123
2R|21|^^^Hb_SL^M|10.000|||||F||1|19980827175800||123
3R|22|^^^Hct_SL^M|24.293|||||F||1|19980827175800||123
4R|23|^^^Na+_SL^M|8.863|||||F||1|19980827175800||123
5R|24|^^^S1_SM^M|201.127|||||F||1|19980827175800||123
6R|25|^^^S2_SM^M|170.187|||||F||1|19980827175800||123
7R|26|^^^S1_M1^M|200.144|||||F||1|19980827175800||123
0R|27|^^^S2_M1^M|169.418|||||F||1|19980827175800||123
1R|28|^^^S1_SL^M|0.770|||||F||1|19980827175800||123
2R|29|^^^S2_SL^M|1.104|||||F||1|19980827175800||123
3L|1|N
```

5.2.3 pHOx Series ABG Calibration

```
1H|\^&|||NOVA^pHOx Plus^I00.05^12343210|||||||1|2000012923380001
2P|1||37
3O|1|||||||||||||Cal|||||||||F35
4R|1|^^^pH_M1^M|19.22|||N||F|||20000129233800||123432104B
5R|2|^^^pH_M2^M|19.15|||N||F|||20000129233800||1234321050
6R|3|^^^pH_M3^M|23.59|||N||F|||20000129233800||1234321056
7R|4|^^^pH_M4^M|53.60|||N||F|||20000129233800||1234321054
0R|5|^^^PCO2_M1^M|-58.74|||N||F|||20000129233800||12343210DE
1R|6|^^^PCO2_M2^M|-45.07|||N||F|||20000129233800||12343210D9
2R|7|^^^PCO2_M3^M||||N||F|||20000129233800||12343210B1
3R|8|^^^PCO2_M4^M||||N||F|||20000129233800||12343210B4
4R|9|^^^PO2_M1^M|-214.04|||N||F|||20000129233800||12343210C6
5R|10|^^^PO2_M2^M|-188.03|||N||F|||20000129233800||12343210F9
6R|11|^^^PO2_M3^M||||N||F|||20000129233800||123432109D
7R|12|^^^PO2_M4^M||||N||F|||20000129233800||12343210A0
0R|13|^^^Hct_M1^M|1949.87|||N||F|||20000129233800||1234321059
1R|14|^^^Hct_M2^M||||N||F|||20000129233800||12343210E8
2R|15|^^^Hct_M3^M||||N||F|||20000129233800||12343210EB
```

```
3R|16|^^^Hct_M4^M|623.01|||N||F|||20000129233800||1234321018
4R|17|^^^Na+_M1^M|43.19|||N||F|||20000129233800||12343210A7
5R|18|^^^Na+_M2^M|||N||F|||20000129233800||12343210AB
6R|19|^^^Na+_M3^M|27.11|||N||F|||20000129233800||12343210A7
7R|20|^^^Na+_M4^M|||N||F|||20000129233800||12343210A8
0R|21|^^^K_M1^M|106.90|||N||F|||20000129233800||123432103E
1R|22|^^^K_M2^M|||N||F|||20000129233800||1234321013
2R|23|^^^K_M3^M|101.44|||N||F|||20000129233800||123432103E
3R|24|^^^K_M4^M|||N||F|||20000129233800||1234321019
4R|25|^^^Ca++_M1^M|70.63|||N||F|||20000129233800||12343210C5
5R|26|^^^Ca++_M2^M|||N||F|||20000129233800||12343210CA
6R|27|^^^Ca++_M3^M|||N||F|||20000129233800||12343210CD
7R|28|^^^Ca++_M4^M|100.95|||N||F|||20000129233800||12343210FD
0R|29|^^^Cl-_M1^M|||N||F|||20000129233800||12343210A9
1R|30|^^^Cl-_M2^M|||N||F|||20000129233800||12343210A3
2R|31|^^^Cl-_M3^M|||N||F|||20000129233800||12343210A6
3R|32|^^^Cl-_M4^M|||N||F|||20000129233800||12343210A9
4R|33|^^^Glu_M1^M|20.75|||N||F|||20000129233800||12343210F0
5R|34|^^^Glu_M2^M|||N||F|||20000129233800||12343210F7
6R|35|^^^Glu_M3^M|50.69|||N||F|||20000129233800||12343210FC
7R|36|^^^Glu_M4^M|196.88|||N||F|||20000129233800||123432103B
0R|37|^^^pH_SL^M|9.55|||N||F|||20000129233800||1234321076
1R|38|^^^PCO2_SL^M|8.77|||N||F|||20000129233800||12343210D7
2R|39|^^^PO2_SL^M|-12.61|||N||F|||20000129233800||12343210E7
3R|40|^^^Hb_SL^M| uc|||A||F|||20000129233800||123432107F
4R|41|^^^Hct_SL^M|31.59|||N||F|||20000129233800||123432100B
5R|42|^^^Na+_SL^M|9.15|||N||F|||20000129233800||1234321095
6R|43|^^^K_SL^M|-2.41|||N||F|||20000129233800||123432102D
7R|44|^^^Ca++_SL^M|31.69|||N||F|||20000129233800||12343210ED
0R|45|^^^Cl-_SL^M|||N||F|||20000129233800||12343210C8
1R|46|^^^Glu_SL^M|18.71|||N||F|||20000129233800||1234321015
2R|47|^^^pH_D1^M|||N||F|||20000129233800||123432107E
3R|48|^^^pH_D2^M|||N||F|||20000129233800||1234321081
4R|49|^^^PCO2_D1^M|||N||F|||20000129233800||12343210DE
5R|50|^^^PCO2_D2^M|||N||F|||20000129233800||12343210D8
6R|51|^^^PO2_D1^M|0.1|||N||F|||20000129233800||1234321025
7R|52|^^^PO2_D2^M|0.1|||N||F|||20000129233800||1234321028
0R|53|^^^Na+_D1^M|11.4|||N||F|||20000129233800||123432105F
1R|54|^^^Na+_D2^M|5.9|||N||F|||20000129233800||123432103A
2R|55|^^^K_D1^M|-4.00|||N||F|||20000129233800||12343210FF
3R|56|^^^K_D2^M|-10.00|||N||F|||20000129233800||123432102F
4R|57|^^^CA_D1^M|0.03|||N||F|||20000129233800||123432100E
5R|58|^^^CA_D2^M|0.13|||N||F|||20000129233800||1234321012
6R|59|^^^CL_D1^M|||N||F|||20000129233800||123432105C
```

```
7R|60|^^^CL_D2^M|||N||F|||20000129233800||1234321056
0R|61|^^^GLU_D1^M|-5|||N||F|||20000129233800||123432100A
1R|62|^^^GLU_D2^M|-14|||N||F|||20000129233800||123432103D
2R|63|^^^pH_V1^M|||N||F|||20000129233800||123432108E
3R|64|^^^pH_V2^M|||N||F|||20000129233800||1234321091
4R|65|^^^PCO2_V1^M||mmHg||N||F|||20000129233800||1234321077
5R|66|^^^PCO2_V2^M||mmHg||N||F|||20000129233800||123432107A
6R|67|^^^PO2_V1^M|149.16|mmHg||N||F|||20000129233800||123432106B
7R|68|^^^PO2_V2^M|0.00|mmHg||N||F|||20000129233800||12343210F9
0R|69|^^^Na+_V1^M|143.00|mmol/
L||N||F|||20000129233800||123432100A
1R|70|^^^Na+_V2^M|72.00|mmol/L||N||F|||20000129233800||12343210D5
2R|71|^^^K_V1^M|4.00|mmol/L||N||F|||20000129233800||1234321012
3R|72|^^^K_V2^M|10.00|mmol/L||N||F|||20000129233800||1234321042
4R|73|^^^Ca++_V1^M|1.00|mmol/L||N||F|||20000129233800||12343210C2
5R|74|^^^Ca++_V2^M|2.00|mmol/L||N||F|||20000129233800||12343210C6
6R|75|^^^Cl-_V1^M||mmol/L||N||F|||20000129233800||12343210E9
7R|76|^^^Cl-_V2^M||mmol/L||N||F|||20000129233800||12343210EC
0R|77|^^^Glu_V1^M|40.00|mg/dL||N||F|||20000129233800||12343210A6
1R|78|^^^Glu_V2^M|200.00|mg/dL||N||F|||20000129233800||12343210D7
2L|1|N05
```

5.2.4 pHOx Series SO2% Calibration

```
1H|\^&|||NOVA^pHOx Plus^I00.05^12343210|||||||1|20000129235200FD
2P|1||37
3O|1|||||||||||||Cal|||||||||F35
4R|1|^^^S1_M1^M|192.12|||N||F|||20000129235200||1234321044
5R|2|^^^S2_M1^M|800.57|||N||F|||20000129235200||123432104C
6R|3|^^^S1_M2^M|536.29|||N||F|||20000129235200||1234321053
7R|4|^^^S2_M2^M|662.53|||N||F|||20000129235200||1234321053
0R|5|^^^S1_M3^M|-14.75|||N||F|||20000129235200||1234321045
1R|6|^^^S2_M3^M|-16.21|||N||F|||20000129235200||1234321041
2R|7|^^^S1_M4^M|59.79|||N||F|||20000129235200||123432102A
3R|8|^^^S2_M4^M|218.27|||N||F|||20000129235200||1234321053
4R|9|^^^S1_SL^M|8.56|||N||F|||20000129235200||1234321011
5R|10|^^^S2_SL^M|10.03|||N||F|||20000129235200||123432105C
6L|1|N09
```

5.2.5 Combined Patient Sample

```
1H|\^&|||NOVA^pHOx Plus^I00.05^12343210|||||||1|20000127134200F9
2P|1||321CD
3O|1|123|1009||||||||||||Arterial|||||||||FB9
4C|1|I|35  SO2% Dependency|IFA
5R|1|^^^pH^M|7.307|||||F||432|20000127133400||12343210B6
6R|2|^^^PCO2^M|45.4|mmHg||||F||432|20000127133400||1234321069
7R|3|^^^PO2^M|124.9|mmHg||||F||432|20000127133400||123432105B
0R|4|^^^Hb^M||mmol/L||||F||432|20000127133400||12343210D7
1R|5|^^^Hct^M||%||<||F||432|20000127133400||123432107F
2R|6|^^^Na+^M|171.9|mmol/L||||F||432|20000127133400||123432100B
3R|7|^^^K^M||mmol/L||<||F||432|20000127133400||12343210BA
4R|8|^^^Ca++^M|0.90|mmol/L||||F||432|20000127133400||12343210F6
5R|9|^^^Glu^M|79|mg/dL||||F||432|20000127133400||1234321052
6R|10|^^^pHTC^T|7.308|||||F||432|20000127133400||1234321086
7R|11|^^^PCO2TC^T|45.3|mmHg||||F||432|20000127133400||1234321037
0R|12|^^^PO2TC^T|124.6|mmHg||||F||432|20000127133400||123432101F
1R|13|^^^HCO3-^C|22.9|mmol/L||||F||432|20000127133400||1234321059
2R|14|^^^BE-b^C|-3.0|mmol/L||||F||432|20000127133400||123432102A
3R|15|^^^BE-ecf^C|-3.6|mmol/
L||||F||432|20000127133400||12343210FE
4R|16|^^^TCO2^C|24.3|mmol/L||||F||432|20000127133400||1234321039
5R|17|^^^SBC^C|19.7|mmol/L||||F||432|20000127133400||1234321003
6R|18|^^^A^C|97.4|mmHg||||F||432|20000127133400||12343210CA
7R|19|^^^a/A^C|1.3|||||F||432|20000127133400||1234321093
0R|20|^^^nCa++^C|0.80|mmol/L||||F||432|20000127133400||123432107F
1R|21|^^^CcO2^C|20.8|mL/dL||||F||432|20000127133400||12343210AA
2R|22|^^^CaO2^C|20.5|mL/dL||||F||432|20000127133400||12343210A7
3R|23|^^^THb^M|9.4|mmol/L||||F||432|20000127133400||111FD
4R|24|^^^HHb^M|0.030|||||F||432|20000127133400||11119
5R|25|^^^O2Hb^M|0.950|||||F||432|20000127133400||1115F
6R|26|^^^SO2%^M|1.0|||||F||432|20000127133400||111C2
7R|27|^^^COHb^M|0.010|||||F||432|20000127133400||11167
0R|28|^^^MetHb^M||||||F||432|20000127133400||11106
1R|29|^^^O2Ct^M|156.0|mL/L||||F||432|20000127133400||1119E
2R|30|^^^O2CAP^M|223.0|mL/L||||F||432|20000127133400||111AF
3R|31|^^^TempP^E|98.5|deg F||||F||432|20000127133400||1234321078
4R|32|^^^BP^M|756.2|mmHg||||F||432|20000127133400||123432104F
5R|33|^^^TempM^M|98.6|deg F||||F||432|20000127133400||1234321082
6R|34|^^^FIO2^D|20.9|%||||F||432|20000127133400||123432102B
7R|35|^^^pH_SM^M||||||F||432|20000127133400||12343210EF
0R|36|^^^PCO2_SM^M||||||F||432|20000127133400||1234321045
```

```
1R|37|^^^PO2_SM^M|||||F||432|20000127133400||1234321004
2R|38|^^^Hct_SM^M|||||F||432|20000127133400||1234321054
3R|39|^^^Na+_SM^M|||||F||432|20000127133400||1234321011
4R|40|^^^K_SM^M|||||F||432|20000127133400||123432107B
5R|41|^^^Ca++_SM^M|||||F||432|20000127133400||123432102C
6R|42|^^^Cl-_SM^M|||||F||432|20000127133400||1234321010
7R|43|^^^Glu_SM^M|||||F||432|20000127133400||123432105E
0R|44|^^^pH_M1^M|23.62|||||F||432|20000127133400||12343210C1
1R|45|^^^PCO2_M1^M|-57.14|||||F||432|20000127133400||1234321050
2R|46|^^^PO2_M1^M|-213.09|||||F||432|20000127133400||123432103D
3R|47|^^^Hct_M1^M|2002.54|||||F||432|20000127133400||123432108E
4R|48|^^^Na+_M1^M|48.30|||||F||432|20000127133400||12343210ED
5R|49|^^^K_M1^M|185.85|||||F||432|20000127133400||123432109C
6R|50|^^^Ca++_M1^M|75.81|||||F||432|20000127133400||123432100E
7R|51|^^^Cl-_M1^M|||||F||432|20000127133400||12343210EF
0R|52|^^^Glu_M1^M|19.35|||||F||432|20000127133400||1234321035
1R|53|^^^pH_SL^M|9.53|||||F||432|20000127133400||12343210B7
2R|54|^^^PCO2_SL^M|9.02|||||F||432|20000127133400||123432100F
3R|55|^^^PO2_SL^M|-12.57|||||F||432|20000127133400||123432102F
4R|56|^^^Hb_SL^M|10.00|||||F||432|20000127133400||12343210CF
5R|57|^^^Hct_SL^M|31.77|||||F||432|20000127133400||1234321057
6R|58|^^^Na+_SL^M|9.05|||||F||432|20000127133400||12343210E0
7R|59|^^^K_SL^M|0.28|||||F||432|20000127133400||123432104F
0R|60|^^^Ca++_SL^M|32.45|||||F||432|20000127133400||1234321023
1R|61|^^^Cl-_SL^M|||||F||432|20000127133400||123432100B
2R|62|^^^Glu_SL^M|19.70|||||F||432|20000127133400||1234321058
3R|63|^^^S1_SM^M|||||F||432|20000127133400||12343210B8
4R|64|^^^S2_SM^M|||||F||432|20000127133400||12343210BB
5R|65|^^^S1_M1^M|58.61|||||F||432|20000127133400||123432109C
6R|66|^^^S2_M1^M|212.42|||||F||432|20000127133400||12343210C6
7R|67|^^^S1_SL^M|8.56|||||F||432|20000127133400||1234321090
0R|68|^^^S2_SL^M|10.03|||||F||432|20000127133400||12343210AC
1L|1|N04
```